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Pressure relieving support surfaces: a randomised evaluation

J Nixon, EA Nelson, G Cranny, CP Iglesias, K Hawkins, NA Cullum, A Phillips, K Spilsbury, DJ Torgerson and S Mason on behalf of the PRESSURE Trial Group

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The research reported in this monograph was commissioned by the HTA Programme as project number 97/06/14. The contractual start date was in May 2000. The draft report began editorial review in February 2005 and was accepted for publication in September 2005. As the funder, by devising a commissioning brief, the HTA Programme specified the research question and study design. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The HTA editors and publisher have tried to ensure the accuracy of the authors' report and would like to thank the referees for their constructive comments on the draft document. However, they do not accept liability for damages or losses arising from material published in this report.

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Abstract

Pressure relieving support surfaces: a randomised evaluation

J Nixon,[1] EA Nelson,[2] G Cranny,[1] CP Iglesias,[2] K Hawkins,[1] NA Cullum,[2*] A Phillips,[1] K Spilsbury,[2] DJ Torgerson[2] and S Mason[1] on behalf of the PRESSURE Trial Group

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Objectives: To determine differences between alternating pressure overlays and alternating pressure replacement mattresses with respect to the development of new pressure ulcers, healing of existing pressure ulcers, patient acceptability and cost-effectiveness of the different pressure-relieving surfaces. Also to investigate the specific additional impact of pressure ulcers on patients' well-being.

Design: A multicentre, randomised, controlled, open, fixed sample, parallel-group trial with equal randomisation was undertaken. The trial used remote, concealed allocation and intention-to-treat (ITT) analysis. The main trial design was supplemented with a qualitative study involving a purposive sample of 20–30 patients who developed pressure ulcers, to assess the impact of the pressure ulcers on their well-being. In addition, a focus group interview was carried out with clinical research nurses, who participated in the PRESSURE (Pressure RElieving Support SUrfaces: a Randomised Evaluation) Trial, to explore the experiences of their role and observations of pressure area care.

Setting: The study took place in 11 hospital-based research centres within six NHS trusts in England.

Participants: Acute and elective patients aged 55 years or older and admitted to vascular, orthopaedic, medical or care of the elderly wards in the previous 24 hours were investigated.

Interventions: Patients were randomised to either an alternating pressure overlay or an alternating pressure mattress replacement, with mattress specifications clearly defined to enable the inclusion of centres using products from different manufacturers, and to exclude hybrid mattress systems (which either combine foam or constant low pressure with alternating pressure in one mattress, or can be used as either an overlay or a replacement mattress).

Main outcome measures: Development of a new pressure ulcer (grade ≥ 2, i.e. partial-thickness wound involving epidermis/dermis only) on any skin site. Also healing of existing pressures ulcers, patient acceptability and cost-effectiveness.

Results: In total, 6155 patients were assessed for eligibility to the trial and 1972 were randomised: 990 to the alternating pressure overlay (989 after one postrandomisation exclusion) and 982 to the alternating pressure mattress replacement. ITT analysis found no statistically significant difference in the proportions of patients developing a new pressure ulcer of grade 2 or above [10.7% overlay patients, 10.3% mattress replacement patients, a difference of 0.4%, 95% confidence interval (CI) –2.3 to 3.1%, $p = 0.75$]. When logistic regression analysis was used to adjust for minimisation factors and prespecified baseline covariates, there was no difference between the mattresses with respect to the odds of ulceration (odds ratio 0.94, 95% CI 0.68 to 1.29). There was no evidence of a difference between the mattress groups with respect to time to healing ($p = 0.86$). The Kaplan–Meier estimate of the median time to healing was 20 days for each intervention. More patients allocated overlays requested mattress changes due to dissatisfaction (23.3%) than mattress replacement patients (18.9%, $p = 0.02$) and more than one-third of patients reporting difficulties associated with movement in bed and getting into or out of bed. There is a higher probability (64%) that alternating mattress replacements are cost-saving; they were associated with lower overall costs (£74.50 per patient on average, mainly due to reduced length of stay) and greater benefits (a delay in time to ulceration of 10.64 days on average). Patients' accounts highlighted that the development of a pressure ulcer could be pivotal in the trajectory from illness to recovery, by preventing full recovery or causing varied impacts on their quality of life.

Conclusions: There is no difference between alternating pressure mattress replacements and overlays in terms of the proportion of patients

developing new pressure ulcers; however, alternating pressure mattress replacements are more likely to be cost-saving. The results suggest that when renewing alternating pressure surfaces or ordering equipment within a rental contract, mattress replacements should be specified; however, overlays are acceptable if no replacement mattress is available. Similarly, patient preferences can be supported, without any great increase in risk, if individual patients request an overlay rather than a replacement mattress. Further research could include a randomised controlled trial comparing alternating pressure mattress replacements and high-specification foam mattresses in patients at moderate to high risk; an accurate costing study to understand better how much pressure ulcers cost health and social services in the UK; and trials in higher risk groups of patients. Also future trials should measure time to ulceration as the primary end-point, since this is more informative economically and possibly also from a patient and clinical perspective.

Contents

List of abbreviations

ADL	activities of daily living
CEAC	cost-effectiveness acceptability curve
CI	confidence interval
CIPFA	Chartered Institute of Public Finance and Accountancy
CRN	clinical research nurse
CTRU	Clinical Trials Research Unit
df	degrees of freedom
DMEC	data monitoring and ethics committee
GLM	generalised linear model
HCA	healthcare assistant
HRQoL	health-related quality of life
ICER	incremental cost-effectiveness ratio
ICU	intensive care unit
ITT	intention-to-treat
LREC	local research ethics committee
MRC	Medical Research Council
MREC	multicentre research ethics committee
NVQ	National Vocational Qualification
OR	odds ratio
PP	per-protocol
PRESSURE	Pressure RElieving Support SUrfaces: a Randomised Evaluation
R&D	research and development
RCN	Royal College of Nursing
RCT	randomised controlled trial
RN	registered nurse
SD	standard deviation
SF-36	Short Form with 36 Items
TMG	trial management group
TSC	trial steering committee
VAC	vacuum-assisted closure
WN	ward-based nurse

All abbreviations that have been used in this report are listed here unless the abbreviation is well known (e.g. NHS), or it has been used only once, or it is a non-standard abbreviation used only in figures/tables/appendices in which case the abbreviation is defined in the figure legend or at the end of the table.

Executive summary

Objectives

The primary objective of the PRESSURE (Pressure RElieving Support SUrfaces: a Randomised Evaluation) Trial was to determine whether there are differences between alternating pressure overlays and alternating pressure replacement mattresses with respect to the development of new pressure ulcers, healing of existing pressure ulcers, patient acceptability and cost-effectiveness of the different pressure-relieving surfaces. The secondary objective was to investigate the specific additional impact of pressure ulcers on patients' well-being.

Methods

Design

A multicentre, randomised, controlled, open, fixed sample, parallel-group trial with equal randomisation was undertaken. The trial used remote, concealed allocation and intention-to-treat analysis. The main trial design was supplemented with a qualitative study involving a purposive sample of 20–30 patients who developed pressure ulcers, to assess the impact of the pressure ulcers on their well-being. In addition, a focus group interview was carried out with clinical research nurses, who participated in the PRESSURE Trial, to explore the experiences of their role and observations of pressure area care.

Setting

The study took place in 11 hospital-based research centres within six NHS trusts in the UK.

Participants

Acute and elective patients aged 55 years or older and admitted to vascular, orthopaedic, medical or care of the elderly wards in the previous 24 hours were investigated. Additional inclusion criteria were: (1) acute and elective patients with activity limitation/existing pressure ulcer on admission, who had an expected length of stay of 7 or more days; were bedfast or chairfast and completely immobile or had very limited mobility and/or had a pre-existing grade 2 pressure ulcer on admission; and gave their written informed consent to participate (or in unconscious or confused patients, the next of kin gave informed written relative assent); and (2) elective surgical patients with no activity limitation/existing pressure ulcer on admission, who were undergoing a surgical procedure with an average length of hospital stay of 7 or more days and/or expected to be bedfast or chairfast and immobile or to have very limited mobility for at least 3 days postoperatively; and gave their written informed consent to participate.

Patients were excluded from the study where they had participated in this trial during a previous admission; had a pre-existing grade 3, 4 or 5 pressure ulcer on admission; were an elective surgical patient with a planned postoperative admission to the intensive care unit; were an elective surgical patient admitted more than 4 days before surgery; slept at night in a chair; or weighed over 140 kg (upper weight limit for overlay mattress) or less than 45 kg (lower weight limit for replacement mattresses with automatic sensor mats).

Interventions

Patients were randomised to either an alternating pressure overlay or an alternating pressure mattress replacement, with mattress specifications clearly defined to enable the inclusion of centres using products from different manufacturers, and to exclude hybrid mattress systems (which either combine foam or constant low pressure with alternating pressure in one mattress, or can be used as either an overlay or a replacement mattress).

Main outcome measures

The primary end-point for the PRESSURE Trial was defined as the development of a new pressure ulcer (grade ≥ 2, i.e. partial-thickness wound involving epidermis/dermis only) on any skin site. Secondary end-points were healing of existing pressures ulcers, patient acceptability and cost-effectiveness.

Results

In total, 6155 patients were assessed for eligibility to the trial and 1972 were randomised: 990 to the

alternating pressure overlay (989 after one postrandomisation exclusion) and 982 to the alternating pressure mattress replacement. Intention-to-treat analysis found no statistically significant difference in the proportions of patients developing a new pressure ulcer of grade 2 or above [10.7% overlay patients, 10.3% mattress replacement patients, a difference of 0.4%, 95% confidence interval (CI) –2.3 to 3.1%, $p = 0.75$]. When logistic regression analysis was used to adjust for minimisation factors and prespecified baseline covariates, there was no difference between the mattresses with respect to the odds of ulceration (odds ratio 0.94, 95% CI 0.68 to 1.29). There was no evidence of a difference between the mattress groups with respect to time to healing ($p = 0.86$). The Kaplan–Meier estimate of the median time to healing was 20 days for each intervention. More patients allocated overlays requested mattress changes due to dissatisfaction (23.3%) than mattress replacement patients (18.9%, $p = 0.02$) and more than one-third of patients reporting difficulties associated with movement in bed and getting into or out of bed. There is a higher probability (64%) that alternating mattress replacements are cost-saving; they were associated with lower overall costs (£74.50 per patient on average, mainly due to reduced length of stay) and greater benefits (a delay in time to ulceration of 10.64 days on average). Patients' accounts highlighted that the development of a pressure ulcer could be pivotal in the trajectory from illness to recovery, by preventing full recovery or causing varied impacts on their quality of life.

Conclusions

There is no difference between alternating pressure mattress replacements and overlays in terms of the proportion of patients developing new pressure ulcers; however, alternating pressure mattress replacements are more likely to be cost-saving.

Implications for healthcare

The results suggest that when renewing alternating pressure surfaces or ordering equipment within a rental contract, mattress replacements should be specified; however, overlays are acceptable if no replacement mattress is available. Similarly, patient preferences can be supported, without any great increase in risk, if individual patients request an overlay rather than a replacement mattress.

Recommendations for research

The following areas are recommended for further investigation.

- A randomised controlled trial could compare alternating pressure mattress replacements and high-specification foam mattresses in patients at moderate to high risk (it may not be possible to answer this question in the UK, where alternating pressure surfaces have become the standard for at-risk patients).
- An accurate costing study should be undertaken to understand better how much pressure ulcers cost health and social services in the UK.
- Trials are needed in higher risk groups of patients, in whom serious pressure ulcers are more common and the consequences greater (e.g. people with spinal cord injuries).
- Future trials should measure time to ulceration as the primary end-point, since this is more informative economically and possibly also from a patient and clinical perspective.

Chapter 1
Introduction

This report contains seven chapters. This introductory chapter sets out the complexity of the area and outlines the need for this trial. The second chapter describes the methodology of the main trial and the substudies (health economic, quality of life and focus group). The next four chapters present the results of the main trial (Chapter 3), the health economic analysis (Chapter 4), the quality of life substudy of patients who have a pressure ulcer (Chapter 5) and the focus group with the clinical research nurses (CRNs) (Chapter 6). The final chapter provides a discussion of the empirical findings and recommendations for future research.

The size of the problem

Pressure ulcers (also known as pressure sores, bed sores and decubitus ulcers) are defined as areas of localised damage to the skin and underlying tissue caused by pressure, shear, friction or a combination of these.[1] A review of 60 studies of pressure ulcer prevalence or incidence in the UK, USA and Canada reported prevalence rates ranging from 4.7 to 32.1% for hospital populations, 4.4 to 33% for community care populations and 4.6 to 20.7% for nursing home populations.[2] The variation in reported rates is likely to be a consequence of the differing baseline risk of the patient populations studied, and the range and effectiveness of the preventive strategies used. Most pressure ulcers are thought to be preventable, although clinicians believe that a proportion is inevitable.[3] The costs of pressure ulceration are not well described. In 1993 it was estimated that pressure ulcer prevention and treatment cost a typical 600-bedded UK general hospital between £600,000 and £3,000,000 per year.[4] One study estimated the cost of treating a stage 4 pressure ulcer at £40,000;[5] however, the robustness of these estimates is unclear.

Pressure ulcer classification

Pressure ulcers vary in severity from erythema of intact skin to tissue destruction involving skin, subcutaneous fat, muscle and bone. A number of classification systems has been developed.[6] The purpose of a pressure ulcer classification system is to standardise record-keeping and provide a common descriptor of ulcer severity for the purposes of clinical practice, audit and research. There have been international attempts to standardise pressure ulcer classification, resulting in consensus between the (then) American Agency for Health Care Policy and Research[7] and the European Pressure Ulcer Advisory Panel[1] in their pressure ulcer classifications.

However, practical difficulties in the use of pressure ulcer classification scales remain. First, it is important that a record is made when no skin damage is observed, and existing scales tend to make no provision for this. Second, if a pressure ulcer is covered by eschar it is not possible to determine accurately the stage of the ulcer until the eschar has been removed and the wound debrided.[7] Third, there are difficulties associated with the clinical assessment and description of non-blanching erythema and some uncertainty as to whether it is truly a pressure ulcer or a precursor of ulceration (grade/stage 1 pressure ulcers). This uncertainty results in variations in the operational definitions of pressure ulceration used in audit and research. Although accurate documentation of patients' skin status, including the presence of non-blanching erythema, is recommended in the clinical environment, researchers often define pressure ulcers as skin damage of grade or stage 2 or greater. Identification of non-blanching erythema is difficult in patients with darkly pigmented skin and the American classification of stage 1 was revised in 1998 to address limitations of the original guideline document.[8]

Prognosis associated with pressure ulcer formation

Few studies have explored the health sequelae of pressure ulceration. One retrospective cohort study examined the relationship between pressure ulceration and death in 19,981 nursing home residents with a mean age of 71 years.[9] Pressure ulceration was associated with a 45% increase in the risk of dying, after adjustment for confounders [relative risk (RR) 1.45, (95% confidence interval

(CI) 1.3 to 1.65)]; however, it seems highly likely that pressure ulceration is a marker of serious illness rather than the cause of death.

Impact of pressure ulceration on quality of life

The literature on the impact of pressure ulceration on quality of life is sparse. CINAHL, MEDLINE and EMBASE were searched in May 2004 using the terms 'pressure ulcers' and 'quality of life', both as free text terms and subject headings, and exploded both terms to include all subheadings. Four relevant articles that included data were found, and are described briefly.

Langemo and colleagues[10] undertook in-depth interviews with people affected by pressure ulceration: four people with a current pressure ulcer and four with a history of pressure ulceration (50% of the sample were spinal cord injured). Seven themes emerged from the transcripts: perceived aetiology of the ulcer, impact on life and need for changes, psychospiritual impact, extreme pain, knowledge and understanding, effect of stressful treatments and the grieving process.

Fox[11] reported the results of in-depth interviews in five people with severe pressure ulcers (those extending into the subcutaneous tissue or deep fascia). In this study, pressure ulcers were associated with pain and perceived by patients as affecting them emotionally, reducing quality of life with concerns around exudate, loss of independence, worries about healing, body image and social isolation.

Franks and colleagues[12] reported a case–control study in which the Short Form 36 (SF-36) and Barthel index were used to compare the health-related quality of life (HRQoL) in 75 people with pressure ulceration and 100 people without ulceration. All people in this study were receiving treatment from community nurses. People with pressure ulcers had poorer physical functioning and social functioning (both domains in the SF-36) than the published age- and gender-matched norms. Activities of daily living (ADL), self-care and mobility, determined using the Barthel index, were lower among people with pressure ulcers. There was no statistically significant difference in the physical or social functioning domains between the people with and without pressure ulcers in this study, although those with pressure ulcers reported more bodily pain. This suggests that people with a pressure ulcer and receiving nursing care in the community have a poorer quality of life than age- and gender-matched norms, but that the impact of a pressure ulcer on HRQoL may be similar to that of other conditions experienced by people receiving community nursing.

Krause[13] surveyed 1017 people with spinal cord injury, of whom 46% reported at least one ulcer, to ascertain how many skin ulcers they had experienced and whether this was associated with the number of days their quality of life had been adversely affected by ulcers, measured using a life situation questionnaire (LSQ). The number of skin ulcers and the numbers of days negatively affected by skin ulceration were both correlated with poorer life adjustment. Since the design was purely correlational, it is not clear whether poorer adjustment was caused by pressure ulceration or whether people who had adjusted less well, for example being more isolated or with reduced self-care, tended to develop more ulcers (e.g. owing to poorer nutrition or mobility).

In summary, as pressure ulceration is itself a consequence of poor health, it would be extremely difficult if not impossible to identify a quality of life impact (using generic quality of life measures) attributable to pressure ulceration rather than co-morbidities. No valid, reliable pressure ulcer-specific HRQoL tool could be identified in the published literature. To develop a deeper understanding of the quality of life impact of pressure ulceration than would be gained from using generic tools in the trial, in-depth interviews were undertaken with patients about their experiences of pressure ulceration.

Risk factors for pressure ulcer development

Risk factors for pressure ulcer development are those characteristics that increase the likelihood of pressure ulcer development. A comprehensive literature search identified 14 cohort studies in hospital populations that have examined the contribution of different risk factors to the risk of developing a pressure ulcer of stage 2 or above.[14–27] The inpatient groups included in these studies vary and include surgical patients, older people and patients on the intensive care unit (ICU). Those factors that appear to be predictive of pressure ulceration can be broadly grouped into those concerning mobility and activity, nutrition, skin, co-morbidities and, in surgical patients, characteristics of the surgical episode (*Box 1*).

BOX 1 *Factors independently and significantly associated with subsequent pressure ulcer formation identified from cohort studies of hospital inpatients*

Mobility and activity
- Bed- or chairbound[17]
- Braden mobility score[23]
- Reduced activity[24]
- Immobility[18]

Nutritional status
- Impaired nutritional intake[17]
- Reduced body weight[18]
- Malnutrition[16]
- Serum albumin[16,19]

Co-morbidities
- History of cerebrovascular accident[17]
- Charlson comorbidity index[14]
- Sickness at admission score[14]
- Bowel/bladder incontinence[15]
- Urinary catheter[16]
- Do not resuscitate order[16]
- Confused[16]
- Poor general condition[24]
- Vascular disease[25]

Skin
- Stage 1 pressure ulcer[16,18]
- Dry sacral skin[18]
- Moisture[26]

Aspects of surgical experience
- Surgery more than 2 days after admission[14]
- Duration of anaesthesia greater than 2 hours[14,25,27]
- Preoperative stay in ICU[14]
- Number of hypotensive episodes[23]
- Amount of preoperative time immobile[23]
- Mean core temperature[23]
- Extracorporeal circulation[27]

The likely importance of several of these factors has been reinforced in similar studies on elderly nursing home patients; for example, difficulty with ambulation and inability to transfer from bed to chair,[17,21] poor nutritional state,[17] difficulty feeding[21] and low dietary protein,[22] stage 1 pressure ulcers[17] and previously healed pressure ulcers.[17,21] In addition, diabetes, peripheral vascular disease, hip fracture, peripheral oedema, urinary incontinence and faecal incontinence, low systolic blood pressure and end-stage disease have been found to be predictive in nursing home patients.[17,21]

Pressure ulcer risk assessment tools

Over the years, many tools have been developed which, it is claimed, aid the identification of patients most at risk of pressure ulcer development. Many of these tools were not based on the risk factors outlined above, but rather on those factors that clinicians felt were likely to be important, based on clinical impression. Most pressure ulcer risk assessment tools have not been properly evaluated in terms of predictive performance.[28] The Braden Scale[29] has probably been subjected to the most evaluation and, although the developers of the scale reported its high predictive validity, several others have failed to replicate these findings.[30] The Braden Scale comprises six domains: sensory perception, moisture, activity, mobility, nutrition, and friction and shear, and a patient is assigned a score of 1, 2 or 3 for friction and shear, and from 1 to 4 for the remaining five domains (with low scores indicating high risk for each variable). Patients scoring 18 points or fewer are deemed to be at high risk of pressure ulcer formation. The recent Royal College of Nursing (RCN) Clinical Practice Guideline on pressure ulcer risk assessment and prevention recommends that risk assessment tools should only be used as an *aide-mémoire* and should not replace clinical judgement.[31]

Pressure ulcer prevention strategies

Pressure ulcer prevention strategies aim to reduce the magnitude and/or duration of pressure (including shear and friction) between a patient and their support surface (the interface pressure). This may be achieved by regular manual repositioning (e.g. two hourly turning) or by using pressure-relieving support surfaces such as cushions, mattress overlays, replacement mattresses or whole bed replacements.

Pressure-relieving cushions, beds and mattresses either distribute the patient's weight over a larger area (constant low-pressure devices) or mechanically vary the pressure beneath the patient, so reducing the duration of the applied pressure (alternating pressure devices).[32] Constant low-pressure devices can be grouped according to their construction (high-specification foam, foam and air, foam and gel, profiled foam, hammocks, air suspension, water suspension and air-particulate suspension/air-fluidised). These devices fit or mould around the body so that the pressure is dispersed over a large area. Alternating pressure devices generate alternating high and low interface pressures between body and support, usually by alternate inflation and deflation of air-filled cells.

A recently updated systematic review of the evidence for pressure-reducing surfaces in pressure ulcer prevention identified 41 randomised controlled trials (RCTs) and reached the following conclusions.[33]

- High-specification foam alternatives (constant low-pressure devices) compared with the standard hospital mattress reduce the incidence of pressure ulcers in high-risk patient populations (including elderly patients with fractured neck of femur). There is no obvious 'best' foam alternative.
- Eight RCTs comparing the effectiveness of constant low-pressure and alternating pressure devices in reducing the incidence of pressure ulcers were individually underpowered to detect clinically important differences at statistically significant levels. Statistical synthesis of these studies identified no statistically significant difference between alternating pressure and constant low pressure in numbers of new ulcers developed.
- Only three studies have compared different types of alternating pressure device, with each examining a unique comparison and none comparing alternating mattress replacements with overlays. The relative effectiveness of the different alternating pressure devices is unknown.
- No studies have compared alternating pressure devices with high-tech constant low-pressure devices, such as low air-loss/air-fluidised therapies.

From a clinical perspective many UK hospitals have replaced standard hospital foam mattresses with high-specification foam (constant low-pressure devices) as standard for some or all clinical specialities, and alternating pressure surfaces are in widespread use. High-tech constant low-pressure devices (such as air-fluidised therapy and low air-loss beds) are generally used for a very small number of patients with complex disease pathologies and clinical management problems. Alternating pressure systems, either overlays or replacement mattresses, are commonly used for people at moderate to high risk of pressure ulceration. One of the important clinical and economic questions is whether alternating pressure mattress replacements (typical purchase price approximately £4000) confer any advantages beyond those of alternating pressure mattress overlays (typical purchase price approximately £1000). This comparison was therefore chosen as the focus of the trial. Major weaknesses in methodological quality were identified in the majority of previous RCTs of support surfaces,[33] including:

- unconcealed allocation
- open outcome assessment coupled with a lack of independent, blinded validation of outcomes
- no intention-to-treat (ITT) analysis
- high loss to follow-up
- unclear baseline comparability.

In addition, most studies were underpowered [the median sample size was 80 (range 12–1166) and only 14 studies described an a priori sample size estimate]. It was imperative, therefore, that this study avoided these common pitfalls.

Chapter 2
Methods

Objectives

The primary objective of the PRESSURE Trial was to determine whether there were differences between alternating pressure overlays and alternating pressure replacement mattresses with respect to:

- the development of new pressure ulcers
- healing of existing pressure ulcers
- patient acceptability of the surfaces
- the cost-effectiveness of the different pressure-relieving surfaces.

The secondary objective was to investigate the specific additional impact of pressure ulcers on patients' well-being.

Trial design

A multicentre, randomised, controlled, open, fixed sample, parallel group trial with equal randomisation was conducted. The main trial design was supplemented with a qualitative study involving a purposive sample of 20–30 patients who developed pressure ulcers, to assess the impact of the pressure ulcers on their well-being. In addition, a focus group study was carried out with CRNs who participated in the PRESSURE Trial, to explore the experiences in their role and observations of pressure area care.

Trial centres

The study was conducted in six NHS trusts in the north of England, including the following 11 research centres:

1. Leeds General Infirmary, Leeds
2. St James's University Hospital, Leeds
3. Seacroft Hospital, Leeds
4. Chapel Allerton Hospital, Leeds
5. York District Hospital
6. North Tees General Hospital
7. Scarborough General Hospital
8. The General Hospital, Hartlepool
9. Aintree University Hospital, Liverpool
10. Bradford Royal Infirmary, Bradford
11. St Luke's Hospital, Bradford.

At study initiation, eight centres (1–8) were set up and patient recruitment commenced in January 2001. Six of these centres continued recruitment until trial closure, with early closure at the General Hospital, Hartlepool, in July 2001 and discontinuation at Scarborough District Hospital in December 2002. Following a funding extension in 2002, three further centres were co-opted, including Aintree University Hospital, Liverpool, Bradford Royal Infirmary and St Luke's Hospital, Bradford. The Aintree and Bradford Hospitals commenced recruitment in February 2003 and May 2003, respectively.

The main role for three of the hospitals involved in the trial was to support follow-up of elderly care and medical trial patients following their transfer from the acute admissions centres. These were Seacroft and Chapel Allerton Hospitals, Leeds, and St Luke's Hospital, Bradford.

Eligibility

Acute and elective patients aged 55 years or over and admitted to vascular, orthopaedic, medical or care of the elderly wards in the previous 24 hours were included in the study. Specific criteria for inclusion and exclusion were as follows.

Inclusion criteria

Acute and elective patients with activity limitation/existing pressure ulcer on admission

Patients:

- had an expected length of stay of 7 or more days
- were bedfast or chairfast and completely immobile or had very limited mobility (*Table 1*) and/or had a pre-existing grade 2 pressure ulcer (*Table 2*) on admission
- gave their written informed consent to participate or, in unconscious or confused patients, the next of kin gave informed written relative assent.

TABLE 1 *Definition of activity and mobility in the entry criteria*[34]

Bedfast	Confined to bed
Chairfast	Ability to walk severely limited or non-existent. Cannot bear own weight and/or must be assisted into chair or wheelchair
Completely immobile	Does not make even slight changes in body or extremity position without assistance
Very limited mobility	Makes occasional slight changes in body or extremity position but unable to make frequent or significant changes independently

TABLE 2 *Skin classification scale*[39]

Grade	Description
0	No skin changes
1a	Redness to skin (blanching)
1b	Redness to skin (non-blanching)
2	Partial-thickness wound involving epidermis/dermis only
3	Full-thickness wound involving subcutaneous tissue
4	Full-thickness wound through subcutaneous tissue to muscle or bone
5	Black eschar

Elective surgical patients with no activity limitation

Patients:

- were undergoing a surgical procedure with an average length of hospital stay of 7 or more days and/or expected to be bedfast or chairfast and immobile or to have very limited mobility (*Table 1*) for at least 3 days postoperatively
- gave their written informed consent to participate.

Exclusion criteria

Patients were excluded from the study where the following criteria applied. They:

- had participated in this trial during a previous admission
- had a pre-existing grade 3, 4 or 5 (*Table 2*) pressure ulcer on admission
- were an elective surgical patient with a planned postoperative admission to ICU
- were an elective surgical patient admitted more than 4 days before surgery
- slept at night in a chair
- weighed more than 140 kg (22 stones; upper weight limit for overlay mattress)
- weighed less than 45 kg (7 stones; lower weight limit for replacement mattresses with automatic sensor mats).

In relation to pre-existing pressure ulcers of grade 3 or above and ICU admissions, these exclusion criteria were defined following consultation with the NHS trust lead nurses from the participating centres. They advised of a lack of equipoise among clinical staff in mattress allocation for the treatment of partial-thickness and full-thickness pressure ulcers and mattress function issues in the ICU (e.g. reinflation time following cardiac arrest), which would preclude the allocation of an overlay mattress.

End-points

Skin classification, pressure ulcer and healing definitions

The classification scale used in the PRESSURE Trial was adapted from international classification scales[1,7] in order to meet practical data collection requirements for the purpose of research (*Table 2*). Specifically, grade 0 (no skin changes) was included to distinguish clearly skin assessment of normal skin from missing data. Grade 5 (black eschar) was included as a separate grade until wound debridement enabled classification by tissue layer. In addition, blanching and non-blanching erythema were recorded and classified as grade 1a and 1b, respectively.[35]

The primary end-point for the PRESSURE Trial was defined as the development of a new pressure ulcer (grade ≥ 2) after randomisation and before discharge or trial completion. This grade of pressure ulcer was decided upon owing to concerns about the reliability and validity of non-blanching erythema, and the need to minimise the potential for bias in the trial, since the assessors were not blind to the mattress allocation.

Although not included in the primary end-point, erythema was classified and recorded. Non-blanching erythema is an important independent predictor of grade 2 pressure ulcer development, increasing the odds approximately six-fold;[18,36] therefore, secondary analysis includes adjustment for grade 1b at baseline.

There is evidence that there are pathological differences between normal skin and blanching erythema[6,36] and for this reason blanching erythema is classified as grade 1a, that is, distinct from normal skin. There is very limited prospective evidence and it is unclear whether blanching erythema is predictive of subsequent pressure ulcer development. These data were primarily used for further exploratory analyses.

There are no validated measures of pressure ulcer healing. The healing of existing grade 2 pressure ulcers was defined as 'complete re-epithelialisation' of the ulcer and was recorded as the resolution of a grade 2 pressure ulcer to normal or erythematous skin (that is, grade 0, 1a or 1b).

Primary end-point

The primary end-point was defined for each patient as the development of a new pressure ulcer (grade ≥ 2) on any skin site (sacrum, buttocks, heels, hips or other) after baseline skin assessment and before trial completion as recorded by the CRN. This included grade 2 damage that developed from grade 1a or 1b skin changes or from skin trauma that was present at baseline. For patients with a wound or bandage/dressing *in situ* at baseline, only ulcers of grade 2 or above developing at other sites were considered as new pressure ulcers.

Trial completion

Trial completion was defined as patients fulfilling one of the following criteria:

- improved mobility and activity (Braden score 3 or 4; Appendix 1)
- grade ≥ 2 pressure ulcer resolved to 1a/0 for 3 consecutive days AND improved mobility and activity (Braden score 3 or 4; Appendix 1)
- transfer to non-participating ward/consultant
- discharge from hospital
- 60 days from randomisation
- death.

Patients with a pressure ulcer of grade 2 or above resolved to a grade 1b remained in the trial as these patients were still considered to be at risk.

Secondary end-points

Healing of existing pressures ulcers

Three end-points were used to assess healing:

- *Median time to healing*: time to event data usually follow a highly skewed distribution, thus it is common practice to use the median statistic rather than the mean. Furthermore, the median is the statistic more commonly represented in the clinical literature. Median time to healing was derived as the number of days between the baseline skin assessment and the first assessment where a grade 0, 1a or 1b was recorded by the CRN. Ulcers that did not heal, for whatever reason (e.g. including patient death), were treated as censored, and time to healing was derived as the number of days between the baseline skin assessment and trial completion (trial completion in this case is the point at which the patient died, completed or left the study).
- *Change in surface area*: all pressure ulcers were traced (using acetate film with a printed grid, using a fine, indelible marker) on a weekly basis by the CRN. The area encompassed by acetate film tracings (from baseline to trial completion) was measured by computerised planimetry using the program 'Mouseyes'. One trial coordinator (GE) measured all tracings and a standardised technique was used to minimise error.
- *Grade of ulcer at trial completion*: pressure ulcer grading systems describe the anatomical depth of an ulcer at the time of assessment. Reverse staging refers to the use of anatomical grading systems in reverse order to describe the process of pressure ulcer healing. This approach has been criticised on the basis that pressure ulcers do not heal through the ordered replacement of lost muscle, subcutaneous fat and dermis before re-epithelialisation.[37] Instead, the defect becomes filled with granulation tissue composed primarily of endothelial cells, fibroblasts, collagen and extracellular matrix. However, in the absence of clinically feasible, reliable and validated mechanisms for monitoring healing, the reverse staging approach was pragmatically applied to give an indication of the reducing anatomical depth of healing pressure ulcers.

Patient acceptability

Two end-points were used to assess patient acceptability:

- among patients who remained eligible for the trial: the numbers of patients requesting to be moved to a 'standard' mattress because they were dissatisfied with the alternating pressure device
- the recording at trial completion of overall comfort and whether or not ('yes' or 'no') patients experienced the following: excessive noise, interference with sleep, mattress motion, difficulty moving in bed, difficulty getting into/out of bed, unacceptable temperature.

Randomisation

A PRESSURE Trial CRN requested patient participation in the trial. Each patient/relative was provided with a verbal explanation of the trial and a written explanation in the form of a patient/relative information sheet (Appendices 2 and 3). Following confirmation of eligibility for trial participation and written informed consent/relative assent, the CRN randomised the patient to receive either a mattress overlay or mattress replacement.

The randomisation was performed using minimisation (dynamic allocation using a prespecified computer-generated algorithm). To maintain allocation concealment, the minimisation algorithm and subsequent treatment assignment was provided through an independent, central, secure 24-hour randomisation automated telephone service by the Clinical Trials Research Unit (CTRU), University of Leeds. Authorisation codes provided by the CTRU were required to access the service. To ensure balanced treatment groups with respect to potential prognostic factors, the minimisation was performed with respect to the factors detailed in *Table 3*, as recorded at the time of randomisation.

TABLE 3 *Minimisation factors*

Factor	Level	
Centre	11	See trial centres listed (p. 5)
Skin condition	2	No pressure ulcer Existing grade 2 pressure ulcer
Ward speciality	3	Vascular Orthopaedic Medical/elderly
Admission type	2	Acute Elective

Interventions

Mattress definitions

Patients were randomised to either an alternating pressure mattress overlay or alternating pressure mattress replacement, with mattress specifications clearly defined to enable the inclusion of centres using products from different manufacturers and to exclude hybrid mattress systems (which either combine foam or constant low pressure with alternating pressure in one mattress, or can be used as both an overlay and a replacement mattress). The mattress specifications for overlay and replacement mattresses were defined as detailed in *Table 4*.

In addition, it was agreed that patients would be randomised to the products used at the time of randomisation by the participating centre, and limited to the main mattress supplier at that centre. A centre requirement was that the majority of mattress provision was through one main company for purchase and/or rental. There are several mattress manufacturers and suppliers, and most NHS hospitals have contractual arrangements with one main company for purchase and/or rental. During trial set-up for centres 1–8 (see p. 5) during 2000, two centres managed their mattresses on a lease/rental only basis and were renewing their mattress provision contracts. The remaining six centres managed a stock of purchased systems and used rental to cover peaks in demand.

The mattress models for use, as well as those excluded from the trial, were specified by centre. Where the main mattress supplier changed during the trial recruitment period, then the defined mattresses for that centre were also changed.

Further, patients were provided with a high-specification foam mattress at trial completion for a 3-day follow-up period. A high-specification

TABLE 4 *Operational mattress definitions*

	Alternating pressure mattress overlay	Alternating pressure mattress replacement
Alternating cell height minimum	3.5 inches (8.5 cm)	8 inches (19.6 cm)
Alternating cell height maximum	5 inches (12.25 cm)	12 inches (29.4 cm)
Cell cycle time	7.5–30 minutes	7.5–30 minutes
Cell cycle	1 in 2 or 1 in 3 or 1 in 4	1 in 2 or 1 in 3 or 1 in 4

foam mattress was defined as a foam mattress with a two-way or all-way stretch vapour-permeable cover.

Mattress provision after randomisation

The PRESSURE Trial CRNs worked closely with ward staff and informed ward staff of the randomised mattress allocation (see Appendix 4 for trial flow diagram). Mattresses were provided as follows:

Acute and elective patients with activity limitation/existing pressure ulcer on admission were randomised and provided with a trial mattress within 24 hours of admission to hospital. Where available, the CRNs provided the patient with the allocated mattress immediately after randomisation. Where ordering a mattress was required (through rental contracts or mattress stores) the CRN ordered the mattress as randomised and asked the ward staff to install the randomised mattress following delivery to the ward.

Elective surgical patients with no activity limitation/existing pressure ulcer on admission were consented to the study and randomised within 24 hours of admission to hospital. Preoperatively, patients were allocated a high-specification foam mattress. They received the trial mattress either on the day before surgery or immediately after surgery at the point of transfer to bed. Where patients received the mattress immediately postoperatively, the CRN liaised with ward and theatre staff as appropriate to ensure allocation of the mattress at the point of transfer to the postoperative bed (either ward or theatre depending on the type of surgery and local theatre/postanaesthetic care practices).

Blinding

This was an open trial. Owing to the nature of the mattresses under investigation, it was not possible to mask the randomised intervention to the patients participating in the trial, ward nursing staff or the CRNs conducting the skin assessments. Options including daily assessments away from the bed, ordinary photography and high-resolution digital photography were considered, but these raised matters of unacceptable inconvenience and burden on patients. To minimise the potential for bias it was planned that qualified ward-based nursing staff (WNs) would record daily skin assessments and CRNs would undertake assessments twice weekly to validate ward staff records, ward staff remaining blind to the CRN record. However, subsequent inter-rater reliability assessments and data quality monitoring identified problems associated with the accuracy and completeness of the WN records. The Trial Steering Committee (TSC) recommended that both WN and CRN records should be continued during the trial, but that the CRN assessments were to be used for the trial analysis. Neither the CRNs nor WNs were informed of this decision (see section 'Data quality and monitoring', p. 12).

Assessments

The following information was collected for all patients who consented to trial participation, and was recorded by the PRESSURE Trial CRNs.

Registration and randomisation

- patient name
- date of birth
- confirmation of written consent
- hospital
- hospital ward
- hospital consultant
- type of admission (acute/elective)
- speciality (vascular/orthopaedic/medical–elderly)
- existing pressure ulcer (yes/no)
- hospital number
- date of admission to hospital
- time of admission to hospital [if admitted through the accident and emergency (A&E) department, time admitted to A&E = time of admission]
- date approached for inclusion in study
- time approached for inclusion in study
- date of planned surgery (elective surgical patients only)
- skin assessment (sacrum, buttocks, heels, hips and other) using the skin classification scale (*Table 2*)
- mobility/activity score using Braden Scale (Appendix 1)
- patient's reported weight.

Postrandomisation assessments

Baseline (at time of mattress provision)

- Skin assessment (sacrum, buttocks, heels, hips and other) using the skin classification scale (*Table 2*) and tracing of existing grade 2 pressure ulcers using acetate film with a printed grid, using a fine indelible marker
- Braden Scale (Appendix 1)
- Mattress checklist, including date of mattress provision, time of mattress provision, manufacturer, model, type of mattress, and

confirmation that the mattress is alternating and working correctly
- baseline assessment of risk factors, including on admission/preoperative serum haemoglobin and albumin (from routine requests), existing wounds (number and type), diabetes and smoking status, and history of weight loss.

Twice weekly up to 30 days and then weekly up to 60 days
- Skin assessment (sacrum, buttocks, heels, hips and other) using the skin classification scale (*Table 2*)
- Braden Scale (Appendix 1)
- mattress checklist, including manufacturer, model, type of mattress, and confirmation that the mattress is alternating and working correctly
- reason for mattress change
- confirmation of continued eligibility
- date(s) of surgery (as recorded in medical notes).

Patients with pressure ulcers
- Tracing of pressure ulcers using acetate film with a printed grid, using a fine indelible marker on a weekly basis
- number of dressing changes and dressings products applied at each dressing change for each pressure ulcer.

At trial completion and/or discharge
- Reason for trial completion, including pressure ulcer healed, improved activity/mobility, discharged from hospital or transfer to non-participating ward/consultant, 60 days from randomisation or death
- patient acceptability questionnaire regarding the comfort of the mattress, including noise, interference with sleep, mattress motion, difficulty moving in bed, difficulty getting into/out of bed, temperature and overall comfort
- discharge destination and district nurse support.

Adverse events and withdrawal
- Adverse event details classified as 'mattress related' and 'not mattress related', with subcategories of fall, cardiac arrest, hyperthermia, hypothermia and other
- reason for withdrawal, including whether patient or nurse initiated.

Trial organisational structure

The TSC, which had an independent chair and two independent advisors (Appendices 5 and 6), was responsible for monitoring the conduct of the trial, according to the Medical Research Council (MRC) guidelines for good clinical practice in clinical trials.[38] The Data Monitoring and Ethics Committee (DMEC), a subcommittee of the main TSC, provided monitoring of safety data.

The trial management group (TMG), led by Professor N Cullum as Chief Investigator (Appendix 7), was responsible for study design, protocol development, clinical set-up and clinical coordination, CRN training, ongoing management and monitoring, promotion of the study, analysis, interpretation and publication of the study. In addition, the collaborative partners within the TMG had the following responsibilities:

- The CTRU, University of Leeds, was the main trial coordinating centre and was responsible for randomisation, data management, data quality, trial coordination, statistical monitoring and analysis of the trial, the inter-rater reliability substudies, and ensuring trial conduct within legal, ethical and good practice frameworks.
- The Department of Health Sciences, University of York, was responsible for the economic evaluation, recruitment to the quality of life substudy, including patient interviews and analysis, focus group interviews with the PRESSURE Trial CRNs and associated data analysis.

An external project team (Appendix 8), comprising a senior nurse from each participating NHS Trust, was consulted on the design and feasibility during set-up, submitted to their respective local research ethics committee (LREC) and research and development (R&D) committees, and provided operational support throughout the trial.

The CRNs (Appendix 8) were coordinated by the CRN team leader and were responsible for dissemination of the protocol and promotion of the study, ward sister and consultant agreements, patient recruitment, obtaining patient consent, randomisation, mattress allocation and coordination of all aspects of data collection.

Ethics issues and research approval

Ethics approval

The study was submitted and approved by the North West Multicentre Research Ethics Committee (MREC) and the LREC of each participating centre before patients were entered into the study.

The study was conducted in accordance with the recommendations guiding physicians in biomedical research involving human subjects, adopted by the 18th World Medical Assembly, Helsinki, Finland, 1964, amended at the 52nd World Medical Association General Assembly, Edinburgh, Scotland, October 2000. It was monitored by the TSC and the DMEC.

Research approval

Agreement to undertake the trial was provided by each participating centre through the R&D approval processes. In addition, written agreement was obtained from all vascular, orthopaedic, medical and care of the elderly consultants and ward sisters/charge nurses before entering patients admitted under their care. Responsibility for care remained with the clinical team. Across the 11 participating centres a total of 270 consultants and 153 ward sisters/charge nurses agreed to the participation of patients admitted under their care.

Informed consent

A PRESSURE Trial CRN requested patient participation in the trial. Each patient was provided with a verbal explanation of the trial and a written explanation in the form of a patient information sheet (Appendix 2) and given the opportunity to ask questions.

Informed written consent was obtained for all patients before randomisation into the study (Appendix 9). The right of the patient to refuse consent without giving reasons was respected. Further, the patients were free to withdraw from the study at any time, again without giving reasons and without prejudicing any further treatment or care.

Assent by relatives

Ethics approval was given to obtain assent from relatives of patients admitted to hospital with an acute illness, at high risk of pressure ulcers, who were unable to give informed consent for reasons including unconsciousness, semi-consciousness and confusion. It was argued that these patients should be included in an evaluation of pressure ulcer prevention surfaces as they are likely to be particularly at risk, and as a corollary of this, constitute a group of patients to whom the results of this trial would be especially applicable.

Hospital care for the prevention of pressure ulcers is currently extremely varied and there is no standard treatment. It was considered that there are minimal risks associated with inclusion in the trial, with patients in both arms of the study receiving mattresses in widespread and common use in the NHS.

Assent from the patient's next-of-kin was obtained where the patient was unable to give informed consent. This involved a full verbal explanation of the study by the CRN, supported by a written information sheet (Appendix 3), and relatives were given the opportunity to ask questions before the written assent (Appendix 10). The right of the patient's next-of-kin to refuse assent without giving reasons was respected. Further, the patient's next-of-kin remained free to withdraw the patient from the study at any time, again without giving reasons and without prejudicing any further treatment or care.

To minimise the potential for conflict within families and risk of complaint, next-of-kin was defined in the first instance as a relative of the patient, either the spouse or offspring. A protocol amendment was subsequently agreed by the MREC (January 2002) and next-of-kin was defined as a relative of the patient and the named next-of-kin as recorded on the front sheet of the patient's hospital or nursing notes. Where there was a lack of clarity regarding the relationship between the patient and next-of-kin (e.g. common-law husband/wife) or potential for conflict between relatives (e.g. where the main carer was not the next-of-kin) assent was not requested. The CRN consulted ward staff regarding family history and relationships and made an informed decision regarding the appropriateness of patient inclusion. If any conflict emerged between family members, at any time, the CRN could withdraw the patient from the trial, documenting relevant details in the ward nursing record and research pro forma.

Where patients subsequently regained their competence to provide consent, this was sought following a full explanation of the study (verbal and written).

Randomisation within 24 hours of admission

Pressure ulcers are incipient by nature, so it was considered important to commence preventive interventions during routine admission procedures. The majority of participating centres had local pressure ulcer prevention policies which advocated risk assessment and allocation of pressure-relieving equipment within 12–24 hours of admission to hospital. Therefore, it was considered essential that for the recruitment of people admitted acutely, randomisation and

mattress provision should be undertaken within the first 24 hours of admission to mirror current best practice, minimise disruption of acutely ill patients and minimise the risk of potential tissue damage arising from other support surfaces, for example. Specific approval was requested from the MREC to consent patients within 24 hours of admission and this was granted.

Data quality and monitoring

Data management and monitoring were conducted to MRC Guidelines for Good Clinical Practice in Clinical Trials[38] and CTRU Standard Operating Procedures. Data management practice included verification, database validation and 100% data checking following data entry. All missing and ambiguous data were chased until resolved. Data quality was assessed by the Senior Trial Coordinator (AP) and Clinical Coordinator (JN). A comprehensive monitoring schedule was established for the trial (Appendix 11), including assessment of inter-rater reliability, data quality, compliance and safety.

Inter-rater reliability

To monitor the quality of data recorded by the PRESSURE clinical CRNs and WNs, interrater reliability was assessed. The aim was to assess the inter-rater reliability of data relevant to the derivation of the primary end-point (the diagnosis of a grade ≥ 2 pressure ulcer) and secondary end-points (skin classification for all grades). The inter-rater reliability was assessed:

- between the CRN coordinator and CRNs working across different research centres:
  - pretrial CRN inter-rater reliability substudy
  - new CRN inter-rater reliability assessments
  - repeat CRN inter-rater reliability assessments
- between CRNs and WNs:
  - pretrial inter-rater reliability substudy
  - trial data inter-rater reliability assessment.

Full details of the methodology and results are detailed in Appendix 12 and the wider implications of the pretrial substudy are reported elsewhere.[39]

Important issues raised by the pretrial inter-rater reliability substudy and assessment of trial data were discussed by the TSC and TMG in April 2002.

The TSC and TMG were reassured that the CRNs working across different research centres were able to assess and record skin observations in a consistent and reliable way. Overall agreement was 100% and the kappa statistics indicate 'very good' agreement between the CRN team leader and the CRNs in the diagnosis of a pressure ulcer. However, there was concern about the level of disagreement between the CRNs and WNs in the classification of skin assessments. Although overall percentage agreement and kappa statistics indicate 'good' agreement between the CRNs and WNs, important disagreements in both the diagnosis of pressure ulcers and skin classification for all grades were concealed by the high prevalence of normal skin with no skin changes. In addition, the inter-rater assessment of trial data highlighted high levels of missing data. In the light of the concerns about the quality of WN data it was recommended by the TSC that the CRN data should be used for the main trial analysis. The advantage of using CRN data was that the data were reliable. The disadvantage was that pressure ulcers of short duration would not be recorded (since CRNs made assessments only every 4 days) and the secondary end-points of time to pressure ulcer development and time to pressure ulcer healing would only be precise to within 3 or 4 days. It was felt that, in relation to the former, if the pressure ulcers are of such short duration they would not be clinically important and, in relation to the latter, this would apply to patients in both groups.

It was also agreed that the WN data should continue to be obtained for the purposes of verification, since skin assessment data were not systematically and routinely recorded in many of the participating clinical areas and source data verification was not feasible. It was also recommended that the change to the statistical analysis plan should remain confidential to the TSC and TMG and not be relayed to the CRN team leader or CRNs. There was a concern that using CRN data for the main analysis would have the potential to introduce bias; it was considered important that the CRNs should not know that their data would have primacy to avoid a change in their behaviour in relation to their assessment and recording of skin observations, and to maintain their motivation to prompt WNs in recording the trial data.

Skin assessment data quality

Several problems were identified in relation to consistency of skin assessments and these were addressed by both feedback to the CRNs and the development of verification rules for the purposes of data analysis as follows.

Grade 3 at baseline

A small number of patients with diabetic foot and ischaemic ulcers at baseline was recruited, but the ulcers were ambiguously recorded as grade 3 ulcers. Recruitment of patients with ulcers of grade 3 or above at baseline was prohibited by the protocol (ward nurses were unwilling to allocate these patients to an overlay mattress and the allocation of an overlay mattress to these patients would not conform with current best practice as defined in hospital policies and guidelines). However, the TSC considered that it would be unethical not to use the data from the small number of patients with a grade 3 ulcer at baseline who had been recruited. These patients therefore remained in analyses with exclusion of the ulcerated skin site in the derivation of the primary end-point. A sensitivity analysis was planned to assess the impact of these patients on the primary end-point analysis.

Skin alteration/trauma/wounds at baseline

A proportion of patients randomised as 'existing pressure ulcer = no' were simultaneously described as having skin trauma or alteration of skin at baseline (recorded descriptively by the CRNs in detail). Where the skin damage was allocated a grade 2 or clearly indicated the presence of a wound at baseline it was agreed that these sites would be excluded from the derivation of the primary and secondary end-points. Similarly, where the result of the skin assessment was missing owing to the presence of a dressing or bandage, the site was excluded from the derivation of the primary end-point.

Interpretation of descriptions was most problematic where the skin alteration had been allocated a grade 0, 1a, 1b or missing and a grade 2 ulcer developed on the site at follow-up. To avoid the need for interpretation of these descriptive data and the bias this might introduce, it was agreed to include all skin sites with skin alteration at baseline in the derivation of the primary end-point, but to code the skin alteration as 'skin trauma' and include this in the adjusted analysis as a covariate. This was supported by further epidemiological data which clearly indicate that skin alteration at baseline is predictive of subsequent pressure ulcer development.[30]

Verification rules were established to classify all skin assessment comments into the following categories: skin trauma at baseline, wound at baseline, pressure ulcer at baseline, dressing at baseline, and comment irrelevant (Appendix 13). Coding was undertaken by two members of the trial team (JN and SM) independently, and differences were resolved through discussion.

Number of pressure ulcers

Where more than one skin break was observed on only one skin site this was recorded as one pressure ulcer (e.g. six small skin breaks at the sacrum were reported as one pressure ulcer).

Skin trauma at follow-up

In some follow-up skin assessments the CRNs recorded a grade 2 ulcer, but provided a possible reason for the skin break (e.g. diabetic ulcer, blister from slipper). It was agreed that all skin sites allocated a grade 2 ulcer at follow-up would be included in the derivation of the primary end-point on the assumption that difficulties in differential diagnosis would be balanced across both groups.

Mattress compliance

Problems associated with mattress compliance were noted through data monitoring, and included patients who were not placed on the randomised mattress at baseline and a large number of mattress changes at follow-up. A standard monitoring report was developed so that assessment could be made regarding the implications of the mattress changes for the trial.

Consent/assent procedures

The number of trial participants with relative assent, subsequent patient consent and completion of the comfort questionnaire was monitored during the trial by the TSC and is summarised in Chapter 3.

Safety

Adverse events were recorded and categorised by the CRNs, who gained information from ward staff and healthcare records. Categories included 'mattress related' and 'not mattress related', with subcategories of fall, cardiac arrest, hyperthermia, hypothermia and other. Adverse events were reviewed by the clinical coordinator, TMG and TSC, who were blind to allocation. There was concern that unwitnessed patient falls occurring in the vicinity of the beds could be due to patients slipping off the bed and could therefore be mattress related. As the data accumulated, adverse events reported by the CRNs as 'not mattress related – falls' were categorised by the TSC as 'equivocal', 'near the bed', 'location unknown' and 'not near the bed'. The category of 'equivocal' was allocated to events that were considered by the TMG/TSC to be potentially related to the mattress. In addition, the clinical coordinator

reviewed all 'not mattress related – other' adverse events and those considered by the clinical coordinator to be of potential importance were highlighted to the TSC. Unblinded safety reports were reviewed 6-monthly by the DMEC.

Statistical methods

Sample size

The sample size calculation was based on the primary end-point, that is, the proportion of patients developing one or more new pressure ulcers (grade ≥ 2). As there was little information available for the expected incidence rate in this patient population, the sample size was calculated for a range of possible incidence rates. With 2000 patients (with complete primary end-point data) the trial would, in a χ^2 test without continuity correction, have at least 80% power at the 5% significance level (two-sided) to detect a 50% reduction in the proportion of patients developing ulcers of grade 2 or above (i.e. 5% in the overlay arm to 2.5% in the replacement arm, 6% to 3%, 8% to 4% and 10% to 5%).

To detect 50% reductions from incidence rates of 3% and 2% with 80% power, 3220 and 4870 patients, respectively, would be required and it was not considered feasible to recruit such numbers of patients when very small differences in low incidence rates are not of clinical relevance. Assuming that 5% of patients would have incomplete data owing to loss to follow-up, it was planned to randomise 2100 patients to achieve the required 2000 patients to test the primary end-point (1000 patients per treatment group).

No formal interim analyses were planned or conducted during the trial.

Analysis methods

All data analyses and summaries were performed using SAS version 8.2 (SAS Institute, Cary, NC, USA). All hypothesis testing was two-sided and conducted at the 5% significance level.

Patient populations

The intention-to-treat (ITT) population consisted of all patients who were randomised once, analysed according to the mattress group to which they were randomised.

The per-protocol (PP) population consisted of all patients who were not protocol violators. Patients who did not satisfy the eligibility criteria, who withdrew from the trial prematurely or who were not placed on the randomised mattress at baseline, were excluded from the PP population. Acute patients who received the randomised mattress more than 36 hours after hospital admission and elective surgical patients who were not placed on the randomised mattress on or before the day of surgery were also excluded from the PP population.

Patients who were placed on the randomised mattress at baseline but who later had a mattress change were included in the PP population. The skin condition of the patient at the time of the first mattress change was included in the primary end-point analysis rather than the skin condition at the time of trial completion. The mattress models were classified as trial overlay, trial replacement, equivalent overlay, equivalent replacement, high-specification foam or other non-trial mattress before analysis (Appendix 14). Patients who changed to an equivalent mattress type (e.g. from a trial overlay to an equivalent overlay) were not treated as having a mattress change, and their skin condition at the time of trial completion was used in the primary end-point analysis.

Primary end-point

The primary end-point of the trial was defined for each patient as the presence/absence of new skin damage grade 2 or above (a pressure ulcer) on any site (sacrum, buttocks, heels, hips or other), occurring after the baseline skin assessment and before trial completion.

Sites with an existing skin grade 2 or above, or a wound or bandage/dressing *in situ* at baseline, were excluded from the primary end-point derivation. A χ^2 test was used to compare the proportions of patients who developed a new pressure ulcer. The proportions of patients developing a new pressure ulcer in each treatment group, together with the difference in proportions and 95% confidence interval (CI), are presented. The primary analysis was conducted on an ITT basis. This analysis was repeated using the PP population and a sensitivity analysis was also performed to assess the effect of including patients who did not satisfy the eligibility criteria, upon the primary analysis.

Logistic regression analysis was used to adjust the analysis of the primary end-point for the minimisation factors (as recorded at randomisation) and covariates that were prespecified in the statistical analysis plan. Adjustment was made for the following covariates

measured at the baseline assessment: 'skin trauma' at any site (Appendix 13), wound at any site, non-blanching erythema (grade 1b) at any site, patient age, Braden nutrition score, haemoglobin level (measured on admission/preoperatively), Braden mobility score and diabetes. The minimisation factors and covariates identified reflect the five key themes that emerge from the risk factor literature, including mobility, nutrition, perfusion, skin condition and age. A treatment by centre interaction term was fitted in the model to assess whether the treatment effect was consistent across centres.

The time to the development of a new pressure ulcer (the first new ulcer for patients developing more than one) was derived as the number of days between the baseline skin assessment and the date of the first occurrence of a new ulcer of grade 2 or above. The median time to ulceration was compared between mattress groups using a log-rank test. This analysis was conducted on the ITT and PP populations. Patients in the ITT population who did not develop a new pressure ulcer were censored at the time of trial completion. Patients in the PP population who did not develop a new pressure ulcer were censored either at the time of trial completion or at the time of the first mattress change, if they changed to a non-equivalent mattress type during the trial.

The proportions of patients who developed a new pressure ulcer within 30 days of randomisation were compared between mattress groups using a χ^2 test. For those patients who developed a new pressure ulcer, the maximum grade of new ulcer is summarised. The total surface area of all new ulcers was calculated at each skin assessment for each patient, from the sum of the individual ulcer areas if a patient had more than one ulcer. The ulcer area data were analysed on a per-patient basis rather than an ulcer basis as some new ulcers spread over more than one skin site (e.g. the sacrum and left and right buttocks) and so some patients had tracings that covered multiple sites. The maximum total area of new ulceration per patient was compared between the mattress groups using a Mann–Whitney *U*-test as the area data were skewed. These analyses were conducted on the ITT and PP populations.

Subgroup analyses

For exploratory purposes it was planned to examine the possibility that the treatment effect, as measured by the primary end-point, differed between ulcer sites and risk level. For ulcer sites, it was of interest whether there was any difference in the treatment effect between patients developing a new ulcer on the heels compared with the torso, and for risk level, between patients 'at risk' and at 'high risk' of developing an ulcer. Patients with an existing grade 2 ulcer were considered to be at high risk. For each analysis (ulcer sites and risk level), a logistic regression model was fitted to the primary end-point, containing terms for mattress group, the variable of interest (site or risk level) and their interaction. The change in model deviance was used to assess the statistical significance of the interaction term.

Secondary end-points

Existing pressure ulcers

Patients with an existing pressure ulcer were defined as those recorded at randomisation as 'existing pressure ulcer = yes' and with a skin grade 2 on any site at the baseline skin assessment. For the subgroup of patients with one or more grade 2 pressure ulcers existing at the baseline skin assessment, time to complete healing was compared between mattress groups using a log-rank test. Patients with more than one existing pressure ulcer at baseline were only considered healed if all existing pressure ulcers healed during the trial period. Patients who did not heal completely were censored at the time of trial completion.

The total surface area of existing ulcers for each patient was calculated from the ulcer tracings at baseline and each follow-up skin assessment where ulcer tracings had been taken. Summary statistics for baseline ulcer area, final ulcer area, absolute and percentage change from baseline are presented by mattress group. Patients who healed were assigned a final total ulcer area of 0 cm^2.

The final grade of existing ulcers at trial completion was summarised on a per-ulcer and a per-patient basis (using the maximum grade at trial completion if a patient had more than one existing ulcer). The maximum grade at trial completion of existing ulcers, on a per-patient basis, was compared between mattress groups using a χ^2 test for trend. All analyses of existing pressure ulcers were conducted on the ITT population.

Patient acceptability

The proportions of patients requesting a mattress change to a standard mattress, owing to dissatisfaction with the trial mattress, were compared between mattress groups using a χ^2 test. This analysis was conducted on the ITT population.

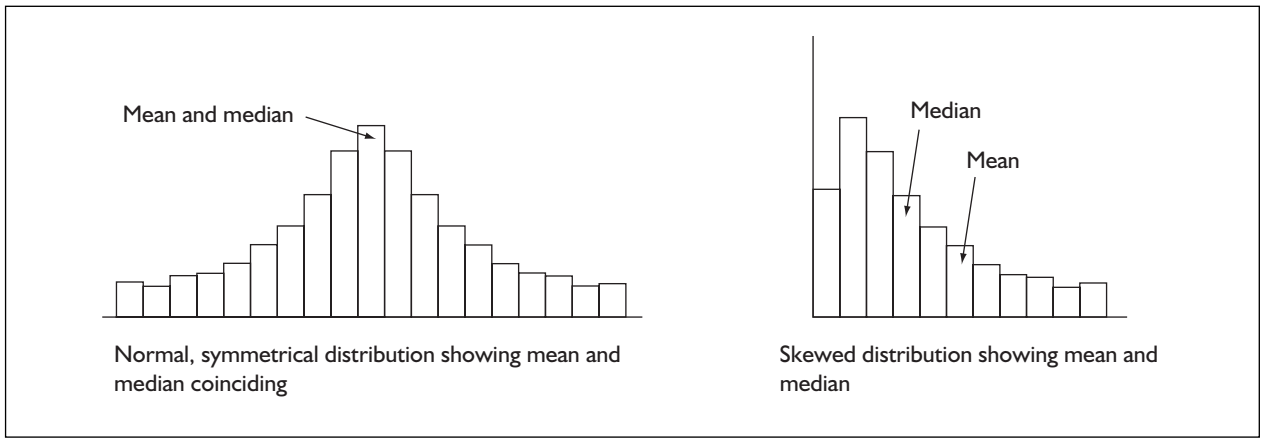

FIGURE 1 *Relationship between mean and median in symmetrical and asymmetrical distributions*

Summaries of the numbers of patients experiencing a problem with each aspect of patient acceptability/mattress comfort as reported on the patient acceptability questionnaire are presented. Comments made by the patients relating to mattress motion, movement, temperature and general issues were reviewed independently by two members of the trial team (JN and SM) and a coding schema was developed (Appendix 15). Comments were then coded independently by both researchers and differences resolved through discussion. Summaries of these descriptive data are presented by the actual mattress on which the patient was placed at the baseline assessment, rather than the randomised mattress.

Cost-effectiveness analysis

A cost-effectiveness analysis was performed using patient-level data. The perspective of the economic analysis was that of the UK NHS and Personal Social Service.[40] The time horizon for the analysis was length of stay in hospital. Neither costs nor benefits were discounted since the time horizon for the analysis was shorter than a year. The pricing year was 2002–03.

Decisions regarding resource allocation should take into account the expected average costs and benefits for a given population, usually represented by the arithmetic means of these variables. Whereas medians and means coincide in a normal, symmetrical distribution, time to event and cost data usually follow skewed or asymmetrical distributions (*Figure 1*). In the clinical analysis, the median time to event is used to describe the time taken for 50% of participants to develop a pressure ulcer; a clinically meaningful statistic that is economically uninformative since it underestimates the average effect in terms of costs and health benefits observed in the whole of the population (*Figure 1*).

Data collection

Dates of entry and discharge from hospital were routinely recorded for each patient. In the event that a patient developed a pressure ulcer, research nurses collected data regarding the number of dressings applied. Data monitoring identified difficulties with the collection of these data, reported to the TSC in April 2003. The TSC recommended that the trial team look at the proportion of patients with pressure ulcers who have a dressing applied and also the costs of different types of dressing. Only a small proportion of patients with pressure ulcers up to and including grade 2 (30%) had a dressing applied, there were only minor differences in cost between different dressings, and nursing records of dressing changes were of poor quality. It was therefore agreed by the TSC in November 2003 that length of hospital stay would be the source of cost data.

Estimation of health benefit

Health benefit was defined as the difference in the mean time to develop a pressure ulcer between mattress groups, that is, 'pressure ulcer-free days'.

Statistical analysis of health benefits

Analyses were performed in Stata® 8.[41] Survival analysis was used to compute restricted Kaplan–Meier estimates of mean time to pressure ulcer development in each trial arm using the information from the primary ITT analysis. Non-parametric bootstrapping techniques were used to estimate the bias-corrected 95% confidence interval of the mean difference in time to pressure

ulcer development between the overlay and mattress replacement groups.

Estimation of cost

To estimate patients' hospital treatment costs, detailed information was collected regarding a number of items.

Cost of alternating pressure-relieving surfaces

The purchasing cost of each surface was estimated based in UK retail prices provided by manufacturers (Huntleigh Healthcare Ltd and Hill-Rom). It was assumed that patients remained on the allocated pressure-relieving surface during their entire hospital stay.

Lifespan of alternating pressure-relieving surfaces

No official information regarding the expected lifespan of either alternating overlays or alternating mattress replacements was available. CRNs participating in the PRESSURE study, NHS supply officials and manufacturers indicated that the lifespan of both alternating pressure-relieving surfaces could potentially be the same. Clinical expert opinion (Trust Leads, see Appendix 8) suggested that mattresses adequately used and maintained could last from 5 to 7 years, provided they are not in constant use. The actual lifespan of alternating pressure-relieving surfaces primarily depends on the way in which they are used. Efficient use of these surfaces would mean using them only for patients at moderate and high risk of developing pressure ulcers. However, clinical experts indicated that in many instances alternating pressure-relieving surfaces, rather than being adequately stored, are left in the wards used by other inpatients who are at lower risk. Such inappropriate use reduces the lifespan of these surfaces possibly to as little as 2 years. The impact of variations in lifespan was explored in sensitivity analyses. The base-case analysis assumed a conservative lifespan of 2 years, which is also the warranty period for the two types of pressure-relieving surfaces under study.

Hospital cost

Length of stay in hospital was estimated as the difference in days between admission and discharge/death dates. Hospital costs per day were calculated based on Chartered Institute of Public Finance and Accountancy (CIPFA) estimates of the cost per patient day in geriatric, orthopaedic and general surgery wards.[42] Total hospital costs were estimated by multiplying hospital cost per day and the length of stay of each patient.

Pressure ulcer management

Based on nurses' indication that no dressings were applied to 70% of patients with pressure ulcers up to and including grade 2, no extra costs associated with pressure ulcer management were considered.

Statistical analysis of costs

Stata 8 was used to perform all the analyses.[41] Given the skewed nature of cost and length of stay data, generalised linear models (GLMs) were used to adjust mean cost estimates by stratification and baseline covariates, as well as a dichotomous variable indicating whether an individual had developed a pressure ulcer within 60 days. The final models assumed a gamma distribution for the data with an identity link function.[43] For models with an identity link the treatment coefficient estimate is the difference between the arithmetic means of the overlay and replacement groups. A power link function was also fitted in the preliminary analysis; however, an analysis of the normal plots of deviance residuals indicated that the data were better explained using an identity link function. The Akaike information criterion (AIC), $-2\times$log likelihood + $2\times$(number of fitted parameters), was used to compare models.[44]

Non-parametric bootstrapping techniques were used to estimate the bias-corrected 95% confidence interval of the mean difference in costs between the overlay and mattress replacement groups.

Economic evaluation

The two pressure-relieving surfaces were then compared in terms of both the costs and the health benefits associated with the technologies using economic evaluation analysis. The exact form that an economic evaluation takes depends mainly on the way in which health benefits associated with the technology are measured, so that the measurement is both clinically and economically relevant.[45] In the PRESSURE Trial the health benefits associated with alternating overlays and replacement mattresses were measured in a natural unit, pressure ulcer-free days. These data were used to conduct a cost-effectiveness analysis, a frequently used type of economic evaluation in which health benefits are measured in natural units.

Incremental analysis

The decision regarding which of the two technologies is more cost-effective is based on the incremental cost-effectiveness ratio (ICER). The ICER is defined by the ratio of the difference in

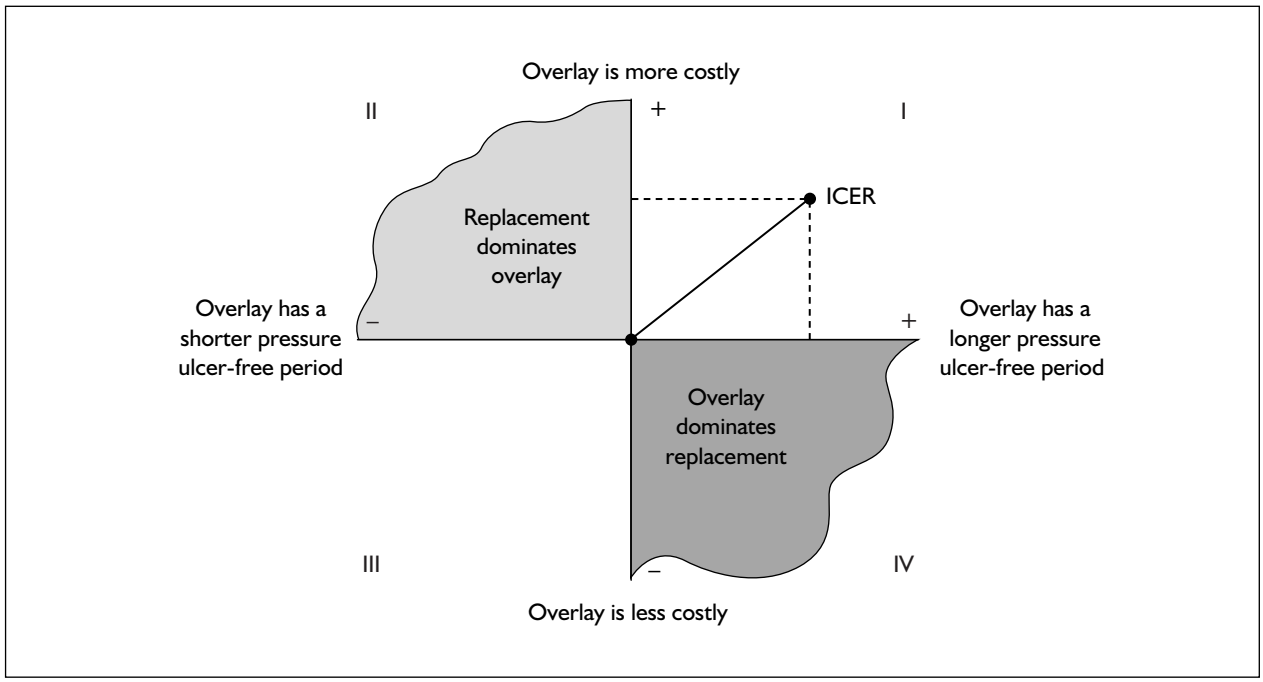

FIGURE 2 *Cost-effectiveness plane*

costs relative to the difference in health benefit associated with the technology under evaluation:

$$\text{ICER} = \frac{C_1 - C_0}{B_1 - B_0}$$

where C_1 = mean cost associated with the technology under evaluation (overlay), C_0 = mean cost associated with the technology of comparison (replacement), B_1 = mean health benefit associated with the technology under evaluation (overlay), and B_0 = mean health benefit associated with the technology of comparison (replacement).

Cost-effectiveness plane

The ICER can be represented in a cartesian plane, better known as the cost-effectiveness plane (*Figure 2*). An incremental analysis is only justified in a situation of absence of dominance, that is, where neither technology under evaluation is dominant (associated with lower costs and greater health benefit than the comparator) or dominated (associated with less health benefit and more costs than the comparator). In other words, an incremental analysis is justified when the ICER does not fall on the second or fourth quadrant of the cost-effectiveness plane (*Figure 2*).

Cost-effectiveness decision rule

When the mean ICER is on either the first or third quadrant of the cost-effectiveness plane, a decision rule is needed. In this case, if the ICER associated with the technology is smaller than the decision-makers' maximum threshold value for an extra unit of health benefit, then the technology under evaluation can be deemed as potentially cost-effective.

Cost-effectiveness acceptability curves

The level of uncertainty associated with the decision to consider alternating pressure-relieving overlays as the cost-effective alternative when compared with alternating replacement mattresses was explored using cost-effectiveness acceptability curves (CEACs). CEACs represent the probability of an alternative being cost-effective for a range of willingness-to-pay values for an extra unit of health benefit associated with the alternative.[46] In this case, the CEAC for alternating pressure relieving overlays represents the probability of overlays being cost-effective compared with replacement mattresses for a range of willingness-to-pay values associated with a pressure ulcer-free day. CEACs allow exploration of the decision uncertainty regarding the cost-effectiveness of an intervention relative to a comparator; for this reason, it has been claimed that they are more useful for decision-making than the confidence intervals associated with the ICER.[46,47]

Sensitivity analysis

The robustness of the results was explored using the scenario approach to sensitivity analysis.[48] Three different scenarios were investigated.

First scenario
All mattresses were considered as rented by hospitals rather than purchased.

Second scenario
The lifespan of both alternating pressure-relieving surfaces was increased from 2 to 5 years, assuming intermittent use.

Third scenario
The lifespan of both alternating pressure-relieving surfaces was increased from 2 to 7 years, assuming intermittent use.

Quality of life

This substudy explored the impact of a pressure ulcer on patients' well-being and the effect of interventions used to prevent and treat pressure ulcers on HRQoL. This research addressed the following questions:

- How do people with pressure ulcers rate their health and quality of life?
- What are patients' experiences of developing a pressure ulcer?
- What are patients' experiences of pressure area care?

The research design of the quality of life substudy consisted of in-depth, semi-structured interviews (see Appendix 17) with men and women, aged 18 years and over, who were in hospital with a pressure ulcer (grade 2–5) and then, where possible, a second interview up to 3 months after hospital discharge.

The follow-up interviews were carried out with patients in their own home after hospital discharge (approximately 3 months later) and investigated the longer term impact of pressure ulcers. The aim of the follow-up interviews was to gain an understanding of the longer term impact of pressure ulcers on patients. In particular, these interviews explored whether a change in pressure ulcer status (such as healing) impacted on their overall quality of life and whether changes in overall health status led to a different emphasis being placed on the impact of the pressure ulcer on HRQoL. In addition, the interviews enabled patients to reflect on their experience of having a pressure ulcer.

MREC and LREC approval was sought and obtained for the qualitative study within the main trial.

Identifying potential participants with pressure damage

CRNs in each of the initial trial centres (Leeds, York, North Tees and Scarborough) notified the researcher of potential participants in the qualitative study. The CRNs visited trial wards daily, and during these visits they asked the ward staff whether anyone on the ward (whether in the trial or not) had pressure ulcers (grade 2–5). The CRN then approached these patients and asked the patient whether they would be willing to speak to a nurse researcher about their pressure ulcer. An information sheet (Appendix 16) was left with the patient if they indicated verbally that they might be interested in taking part. The CRN informed the researcher (EAN/KS) of the name and location of the patient, as well as the site and degree of pressure damage as reported by the ward staff. The researcher then contacted the ward to arrange a convenient time to meet the patient.

At the first meeting the researcher ensured that the patient had had an opportunity to read the information sheet, and answered any questions or concerns raised by the patient. If the patient had not read the information sheet, the researcher spent time reading it with them or waited for them to read it.

When both the patient and researcher were satisfied that there were no outstanding questions or concerns, the researcher confirmed whether the patient was happy to proceed and, if so, completed the consent form. Written consent was obtained from all participants.

Interviews

A semi-structured schedule was used to guide the interview (Appendix 17). This provided the opportunity for the researcher to follow up comments and issues raised by the patient, exploring these in greater depth, investigating apparent inconsistencies, and checking meaning and understanding. The interviews were tape-recorded with the patient's consent. The interviews were transcribed verbatim.

Following completion of the interview, the researcher gained consent from the patient to contact them in about 3 months to arrange a follow-up interview. Patient contact details were confirmed at this stage. Approximately 10 weeks after the first interview, the researcher contacted the CRN who had made the patient referral to confirm that the patient had been discharged from hospital and the date of discharge as recorded in the patient's medical notes. If discharged, a letter

was sent to the patient inviting them to participate in a second interview at a time and place convenient for them (Appendix 18). These appointments were confirmed by mail (a stamped addressed envelope was provided with the letter) or by telephone. If no reply was received in 2 weeks, then a second letter was sent to them. If the patient was still in hospital, the researcher contacted the CRN 4 weeks later to check the date of discharge. If discharged then the procedure detailed above was carried out.

Checking the discharge status of patients was also important so that the researcher was aware of patients who had died before discharge so that letters were not sent out. This process did not, however, inform the researcher of patients who died postdischarge.

Analysis of the qualitative data

Data analysis was carried out principally by KS and findings were discussed with EAN. The qualitative interview data were analysed according to the broad principles and techniques of grounded theory.[49] This process is represented by four sequential stages: developing coding schema, refining codes, achieving saturation and cross-case themes analysis.

Word-processed transcripts were imported as rich text into QSR NUD*IST NVivo package (Version 2) to enable data management. Once imported, each transcript was initially coded according to four descriptive (first level) codes:

1. patients' perceptions of their health
2. patients' perceptions of their quality of life
3. patients' experiences of developing a pressure ulcer
4. patients' experiences of pressure area care.

The next stage of analysis attempted to ensure that data analysis were complete or saturated and was more interpretive, to capture dimensions within the first level codes. Strauss and Corbin[50] define saturation as the stage where "no new information seems to emerge during coding, that is when no new properties, dimensions, conditions, actions or interactions or consequences are seen in the data."

Cross-case thematic analysis involved establishing themes that occurred across the patient interviews. Such analysis is important to establish the extent to which themes are consistent across all patient groups and where there are particular differences, such as between different ages of patients, the location of the pressure ulcer or cause of admission. Cross-case thematic analysis is an iterative process involving several stages: noting patterns and themes, clustering, counting, making contrasts and comparisons, noting relationships, and regrouping data into new categories.

Focus group substudy

As the trial developed, regular CRN meetings raised interesting issues relating to standards of usual pressure area care, variation in attitudes of clinical staff to the research and their perceived role in it, and the 'lived experience' of being a research nurse. The researchers thought it important to try to capture these more formally, and therefore a focus group interview was conducted. A focus group was carried out with CRNs, participating in the PRESSURE Trial. The focus group offered an opportunity for the CRNs to share both their experience of their role and their observations of pressure area care. The specific aims of the focus group with the CRNs was to explore their:

1. general experiences of being a CRN in the PRESSURE Trial
2. observations of pressure area care related specifically to the PRESSURE Trial
3. general observations of pressure area care in clinical practice settings.

It was anticipated that findings from the focus group would be useful to explore, and perhaps help to explain, possible findings of the PRESSURE Trial.

Method

Focus groups are unstructured interviews with small groups of people who interact with each other using the group dynamics to stimulate discussion, gain insights and generate ideas in order to pursue a research topic in depth.[51] Group interactions provide a distinctive type of data because, rather than people simply responding to questions, they are encouraged to talk to one another, ask questions, exchange anecdotes, and comment on each other's experiences and points of view.[52–55] In doing so, the aim of a focus group is to help people to explore and clarify their views through group processes and in ways that would be less easily accessible in a one-to-one interview.

Focus groups may be used at any stage during the research process, depending on their purpose.[56] The focus group with CRNs was conducted

towards the end of the PRESSURE Trial, but before data analysis. A series of open-ended questions encouraged the CRNs to explore their role and observations of pressure area care by pursuing issues of importance to the group, generating further questions, discussion and debate in their own vocabulary. Focus group discussions enable examination of the many types of communication that are used in day-to-day interaction.[54] They also include jokes, anecdotes, teasing and disagreements among participants, revealing insights and dimensions not easily exposed by more conventional one-to-one interviews. The analysis of humour, consensus and dissent, and the use of different types of narrative within the group, enables identification of shared and common knowledge and cultural values.[57]

This focus group was predominantly concerned with aims 2 and 3: the CRNs' observations of pressure area care. Aim 1 provided an opportunity to gather information about the participants and acted as a useful warm-up by helping the CRNs to talk about their role and to share and identify with each other's experiences.

Criticisms of focus groups include group dynamics; that is, the presentation of group ideas potentially silences individual voices of dissent and the presence of research participants may compromise the confidentiality of the research session.[54] However, it should not be assumed that groups are inhibiting relative to the supposed privacy of an interview. Focus groups can facilitate discussion of taboo subjects and participants can be mutually supportive.[58]

Sampling and group composition

Participants were purposively selected as a group to represent CRNs willing to contribute to the focus group discussion. All CRNs employed for the PRESSURE Trial between 2001 and 2004 (n = 16) representing the six participating NHS trusts (including the 11 research centres) were approached by letter as potential participants in the planned focus group (Appendix 19). The letter emphasised that the CRNs, because of their central role in the trial, had valuable experiences, observations and contextual details of direct relevance for the reporting of the trial. The letter was distributed by the CTRU to all CRNs involved in the trial, including those in post at that time and those who had left their PRESSURE Trial CRN position. Nine CRNs (from five NHS trusts, working across nine research centres) participated in the focus group discussion.

CRNs working at the two research centres not represented at the focus group were approached for a telephone interview. The letter (Appendix 20) was sent to them by the CTRU. However, neither nurse at these centres responded and so it was not possible to check whether issues raised by the focus group also related to these unrepresented centres. It was also not possible to gather data about any additional insights (not already highlighted by the focus group) that were of particular importance for the unrepresented centres.

Data collection

The group interview was carried out on a day when the CRNs were meeting at the CTRU for a scheduled research meeting. It was assumed that by incorporating the focus group into this meeting, the CRNs were more likely to attend because they were geographically dispersed across the north of England. The CRNs had been together in the scheduled meeting for about an hour before the focus group discussion took place. The focus group was convened in a meeting room at the CTRU around a boardroom table. The room was familiar to the participants and refreshments were available.

The role of the researcher as facilitator is central to the focus group method. It is generally agreed that facilitators require substantial interpersonal skills, such as the ability to listen, avoid personal involvement in discussion and encourage participants to talk.[53,59] The facilitator (KS) had prior experience of conducting focus groups and she was a registered nurse (RN).

The CRNs were sent information about the purpose of the interview in advance of the meeting. The facilitator ensured that informed consent was obtained from each of the participants before commencement of any group discussion (Appendix 21) and permission sought from the participants for tape-recording of the discussion. The co-facilitator (EP) also recorded field notes, detailing main points raised during the discussion, interactions between participants and any non-verbal behaviour. These field notes supplemented the transcription of the group discussion. A loose structure was followed to guide the focus group (Appendix 22), but it was emphasised that the aim of the discussion was to encourage the CRNs to talk to each other, rather than to address a researcher. As discussion among the participants progressed, the facilitator adopted a more interventionist style, urging participants to continue a debate and to encourage discussion of

any inconsistencies between participants or expressed by an individual.

Data analysis

The tape-recording was transcribed verbatim, although it was difficult at times to capture the exact words of participants when two or more CRNs entered into a debate or discussion. It was recorded on the transcript where participants were interrupted and where such group discussions occurred. The transcript was imported from a Word document into QSR NUD*IST NVivo package (Version 2) for data management and coding.

Minimal guidance exists for the analysis of focus group data and analytical method is often poorly reported in many publications.[60,61] There is also controversy about whether the individual or the group is the unit of analysis in focus group interviews.[60,62,63] This study has used both the individual and the group as the focus for analysis by using flexible analytical approaches to identify the influence of the group on individual participant(s), and vice versa, before drawing conclusions.

Catterall and Maclaren[64] recommend that 'on-screen' coding, using qualitative data analysis computer packages such as NUD*IST, is used for the analysis of focus group content, but that 'off-screen' coding, reading through hard copies of the transcripts, is used for analysing the focus group processes. Analyses were performed by KS in consultation with the research team (NC, AN and EP). The method of content analysis used for this study followed the broad principles of analytical induction.[65,66] The purpose of the method is to derive propositions that apply generally across all data and by focusing on deviant cases, those that appear to contradict the analytical proposition. An important issue when coding and assigning themes was determining when a coded theme was an issue for the group or merely a strongly held viewpoint of one or a few members. Group processes and interactions were analysed by reading the transcript several times and tracing an individual's text in the context of other participants' text.[64] For example, arguments relating to a particular issue stimulating others to rethink their position could be coded on a range of dimensions such as strength of response provoked or the type and range of emotions evoked. In addition, participants can be traced from beginning to end to identify a change in their position or disagreement with the group.

A distinct feature of focus group analysis is the need to indicate the impact of group dynamic and the interplay and modification of opinion that occurs during discussion.[54,67] Focus group reports are often criticised for their lack of attention to interaction in the analysis, despite this being a central component and justification for the use of the focus group method.[62,68] The focus group has been analysed to reflect both content and processes. The coding of the transcript has included attention to types of narrative, such as jokes and anecdotes, and types of interactions, such as questions, deferring to the opinion of others, censorship or change of mind. The data are also presented to include illustrative quotations and, importantly, examples of talk between participants.

Follow-up telephone interviews post-focus group

Analysis of the focus group raised further questions and identified gaps in the discussion. In particular, there had been an overwhelming focus on the negative experiences of the CRNs (despite the facilitator emphasising the importance of addressing both positive and negative experiences) and there had been no discussion about pressure ulcer dressings (the focus had been on prevention rather than treatment). It was not possible to convene another focus group and so the research team decided to carry out follow-up telephone interviews with a CRN from each of the represented centres ($n = 5$).

Letters were sent to all the CRNs by the Leeds CTRU. These letters invited the CRNs to contact the researcher to organise a suitable time for a telephone interview (Appendix 23). At the same time, CRNs who had worked at the two centres not represented at the focus group ($n = 2$) were approached again by letter (sent to them by Leeds CTRU) for a telephone interview (Appendix 20). Of the five CRNs who had participated in the focus group, three of them contacted the researcher. Telephone interviews were carried out with two of these participants; it was not possible to organise an interview with the third despite repeated contact by telephone and e-mail. Neither of the unrepresented centre CRNs contacted the researcher.

The two telephone interviews lasted for approximately 30 minutes and had five main aims:

- to provide an opportunity for the CRNs to comment on the focus group experience

- to ensure that the CRNs felt that they had the opportunity to share their experiences and observations
- to allow the CRNs an opportunity to make further contributions if they felt that there were experiences and observations that they did not have the chance to share during the focus group
- to provide an opportunity for the researcher to ask some specific questions arising from the analysis and to check out some of the emerging findings
- to provide an opportunity for the researcher to ask the CRNs about the treatment of pressure ulcers.

The telephone interview was tape-recorded using a pick-up microphone. The tapes were then listened to by the researcher and transcribed where CRNs offered additional information related to the above aims. Data generated from these interviews are incorporated into the focus group findings chapter (Chapter 6).

Chapter 3

Clinical results

Sample size

In total, 1972 patients were randomised between January 2001 and April 2004. Ten of the 11 centres randomised patients in the trial; *Figure 3* shows the number of patients randomised by centre. The number of patients recruited per centre ranged from 13 to 467.

Analysis populations

The numbers of patients randomised to each mattress for the intention-to-treat (ITT) and per-protocol (PP) populations are summarised in *Table 5*.

TABLE 5 *Number of patients in each analysis population*

	Overlay	Replacement	Total
ITT population	989 (50.2%)	982 (49.8%)	1971
PP population	781 (50.7%)	759 (49.3%)	1540

ITT population

There was one postrandomisation exclusion from the ITT population: one patient had taken part in the trial during a previous hospital admission and therefore data from their second randomisation were excluded from the analysis. The ITT population contains 1971 patients. All analyses and summaries for the ITT population are by randomised mattress.

PP population

Table 6 summarises the number of patients excluded from the PP population and the reasons for exclusion (one reason for each patient). In total, 431 (21.9%) patients were excluded from the PP population; the number of exclusions for the overlay and replacement groups were similar. Four patients did not meet the trial eligibility criteria, with two not being admitted to hospital in the previous 24 hours, one admitted more than 4 days before planned surgery and one randomised in error by the CRN when they had already been discharged. Eighty-five (19.8%) patients were

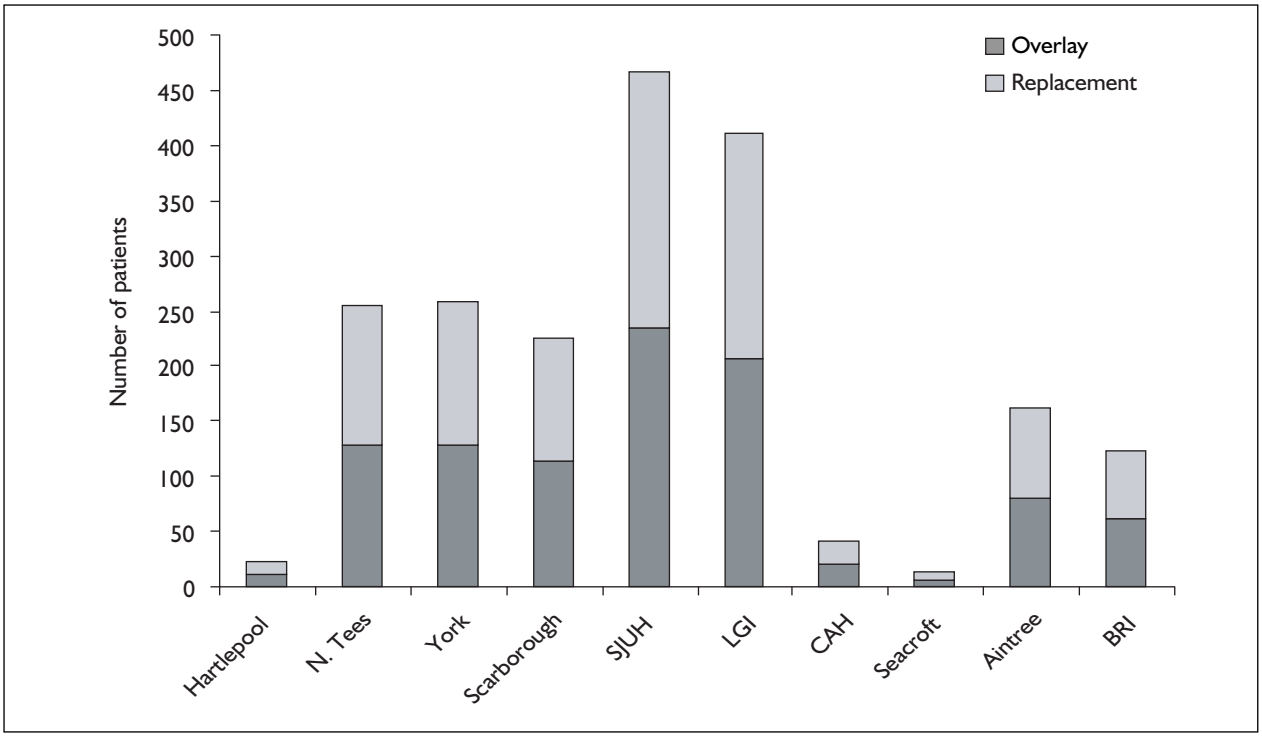

FIGURE 3 *Recruitment by centre. Key to trial centres: N. Tees, North Tees; SJUH, Leeds St James's University Hospital; LGI, Leeds General Infirmary; CAH, Leeds Chapel Allerton Hospital; BRI, Bradford Royal Infirmary.*

TABLE 6 *PP population exclusions*

	Overlay (*n* = 989)	Replacement (*n* = 982)	Total (*n* = 1971)
Excluded from PP population *n* (% of total)	208 (21.0%)	223 (22.7%)	431 (21.9%)
Reason for exclusion			
Violates eligibility criteria	1 (0.5%)	3 (1.3%)	4 (0.9%)
Patient withdrawal	16 (7.7%)	5 (2.2%)	21 (4.9%)
Mattress delay (acute)[a]	21 (10.1%)	31 (13.9%)	52 (12.1%)
Mattress delay (elective)[b]	13 (6.3%)	20 (9.0%)	33 (7.7%)
Randomised mattress not received	157 (75.5%)	164 (73.5%)	321 (74.5%)

[a] Acute patients who received their mattress >36 hours after admission.
[b] Elective patients who were not placed on the mattress on or before the day of surgery.

excluded because of a delay in being provided with the randomised mattress.

Relative assent

Relative assent was given for a total of 87 patients. Assent was provided by the patient's daughter for 48 patients, wife for 13 patients, husband for ten patients, son for 13 patients, granddaughter for one patient, brother for one patient and daughter-in-law for one patient. Of these patients, eight were also able subsequently to provide consent for trial participation themselves.

Trial conduct

A CONSORT (Consolidated Standards of Reporting Trials) flow diagram of trial progress is presented in *Figure 4*. Patients with no postbaseline skin assessments were classed as lost to follow-up.

Table 7 summarises the numbers of patients who withdrew from the trial and the primary reasons for withdrawal. A total of 21/1971 (1.1%) patients withdrew prematurely from the trial and there were more withdrawals in the overlay group (n = 16, 1.6%) than in the replacement group (n = 5, 0.5%). More withdrawals in the overlay group were at the patient's request (12/16, 75%) compared with two out of five (40%) for the replacement group. Six (31.6%) patients in the overlay group requested withdrawal from the trial because of discomfort, whereas no patients in the replacement group withdrew because of discomfort. The main reason given for the CRN withdrawing a patient from the trial was because the patient refused to have their skin assessed.

Table 8 summarises reasons for trial completion. Most patients (65.3%) completed the trial because of improved activity and mobility, corresponding to 63.9% of patients in the overlay group and 66.8% of patients in the replacement group. Once a patient was no longer eligible to remain in the trial, they were transferred onto a high-specification foam mattress.

Table 9 summarises hospital discharge information. This gives details of the destination, whether a district nurse was arranged and the total length of stay in hospital from admission to discharge. A total of 1787 (90.7%) patients had discharge information recorded on the discharge form and most (85.1%) were discharged home. Patients without discharge information had either died, withdrawn from the trial or had their surgery cancelled, or were still in hospital at trial closure.

Baseline characteristics

Tables 10–19 summarise the baseline characteristics, including minimisation details, patient characteristics, clinical details, skin condition assessments and Braden scores for the ITT and PP populations. The two mattress groups were well balanced with respect to baseline characteristics. The PP population was very similar to the ITT population with respect to baseline characteristics.

Tables 10 and *11* summarise the minimisation factors for the ITT and PP populations, respectively. The numbers of acute and elective admissions were similar in the ITT population, with 971 (49.3%) acute admissions and 1000 (50.7%) elective. Most patients (n = 1564, 79.4%) were admitted to an orthopaedic ward, with 333 (16.9%) patients admitted to a medical/elderly ward and 74 (3.8%) patients admitted to a vascular ward. A total of 113 (5.7%) patients already had an existing grade 2 pressure ulcer at randomisation.

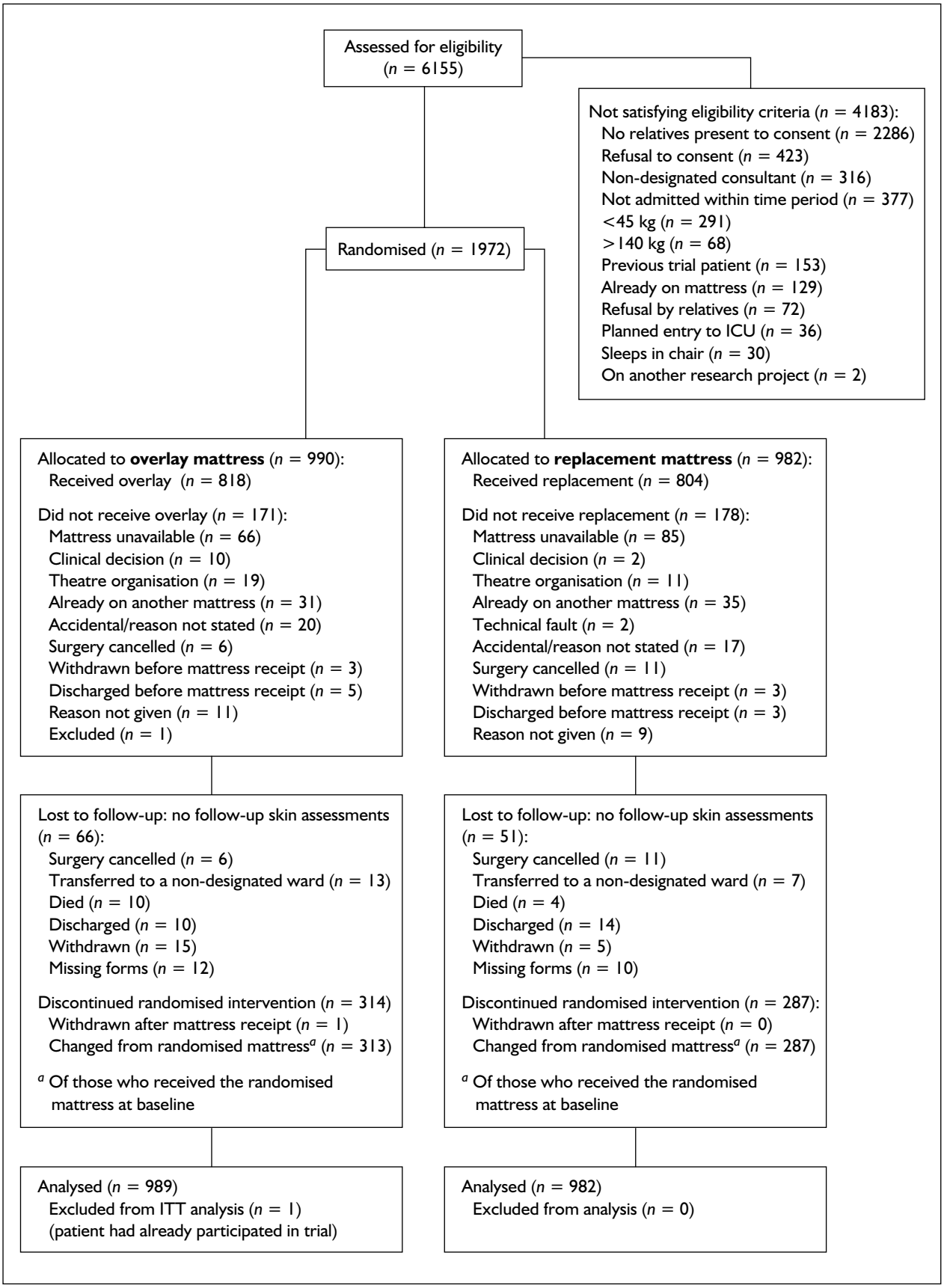

FIGURE 4 *CONSORT diagram*

TABLE 7 *Reasons for patient withdrawal*

	Overlay (*n* = 989)	Replacement (*n* = 982)	Total (*n* = 1971)
Patients withdrawn	16 (1.6%)	5 (0.5%)	21 (1.1%)
Reason for withdrawal			
Patient request	12 (1.2%)	2 (0.2%)	14 (0.7%)
Research nurse decision	4 (0.4%)	3 (0.3%)	7 (0.4%)
Reason for patient requesting withdrawal[a]			
Comfort	6 (0.6%)	0 (0%)	6 (0.3%)
Refusal on readmission	2 (0.2%)	1 (0.1%)	3 (0.2%)
Refused nursing assessment	5 (0.5%)	0 (0%)	5 (0.3%)
Other mattress related	5 (0.5%)	0 (0%)	5 (0.3%)
Consent withdrawn by relative	0 (0%)	1 (0.1%)	1 (0.1%)
Patient distress/confusion	1 (0.1%)	0 (0%)	1 (0.1%)
Reason for research nurse decision to withdraw[a]			
Refused skin assessment	3 (0.3%)	4 (0.4%)	7 (0.4%)
Patient distress/confusion	1 (0%)	2 (0.2%)	3 (0.2%)
Mattress not available	1 (0.1%)	0 (0%)	1 (0.1%)
Surgery cancelled	1 (0.1%)	1 (0.1%)	2 (0.2%)
Other	1 (0.1%)	0 (0%)	1 (0.1%)
Trial duration (days) from randomisation to withdrawal			
Mean (SD)	2.4 (3.4)	1.0 (1.7)	2.0 (3.1)
Median (range)	1.0 (0.0–13.0)	0.0 (0.0–4.0)	1.0 (0.0–13.0)
Missing	0	0	0

[a] Each patient may have more than one reason for withdrawal.

TABLE 8 *Reasons for trial completion*

	Overlay (*n* = 989)	Replacement (*n* = 982)	Total (*n* = 1971)
Reason for trial completion			
Activity/mobility score of 3 or 4	632 (63.9%)	656 (66.8%)	1288 (65.3%)
Pressure ulcer grade 2 resolved AND activity/mobility score 3 or 4	22 (2.2%)	27 (2.7%)	49 (2.5%)
Early completion[a]	5 (0.5%)	5 (0.5%)	10 (0.5%)
Transferred to a non-designated ward/consultant	88 (8.9%)	65 (6.6%)	153 (7.8%)
Length of stay >60 days	31 (3.1%)	29 (3.0%)	60 (3.0%)
Died	55 (5.6%)	45 (4.6%)	100 (5.1%)
Surgery cancelled	6 (0.6%)	11 (1.1%)	17 (0.9%)
Patient withdrawn	16 (1.6%)	5 (0.5%)	21 (1.1%)
Discharged	134 (13.5%)	133 (13.5%)	267 (13.5%)
Reason not given	0 (0.0%)	6 (0.6%)	6 (0.3%)
Trial duration from randomisation to completion (days)			
Mean (SD)	12.2 (11.2)	12.1 (10.9)	12.2 (11.0)
Median (range)	9.0 (0.0–62.0)	8.0 (0.0–63.0)	9.0 (0.0–63.0)
Missing	0	0	0

[a] Patients completing trial early in error when still eligible, or who were still eligible when the trial closed.

TABLE 9 *Hospital discharge*

	Overlay (*n* = 989)	Replacement (*n* = 982)	Total (*n* = 1971)
Number of patients discharged	886 (89.6%)	901 (91.8%)	1787 (90.7%)
Destination (% discharged patients)			
Home	751 (84.8%)	770 (85.5%)	1521 (85.1%)
Residential home	36 (4.1%)	30 (3.3%)	66 (3.7%)
Nursing home	69 (7.8%)	65 (7.2%)	134 (7.5%)
Other NHS hospital	28 (3.2%)	33 (3.7%)	61 (3.4%)
Details not given	2 (0.2%)	3 (0.3%)	5 (0.3%)
Was a district nurse arranged?			
Yes	346 (39.1%)	344 (38.2%)	690 (38.7%)
No	531 (59.9%)	545 (60.5%)	1076 (60.2%)
Details not given	9 (1.0%)	12 (1.3%)	21 (1.2%)
Length of stay (days) from admission to discharge			
Mean (SD)	20.1 (24.7)	18.9 (21.4)	19.5 (23.1)
Median (range)	11.0 (0.0–224.0)	11.0 (0.0–204.0)	11.0 (0.0–224.0)
Missing	0	0	0

Summary for discharged patients only; patients with missing discharge information had either died (*n* = 152), withdrawn with no subsequent discharge data (*n* = 15) or had surgery cancelled with no subsequent discharge data (*n* = 10), or were still in hospital at trial closure (*n* = 7).

TABLE 10 *Minimisation details (ITT population)*

	Overlay (*n* = 989)	Replacement (*n* = 982)	Total (*n* = 1971)
Type of admission			
Acute	488 (49.3%)	483 (49.2%)	971 (49.3%)
Elective	501 (50.7%)	499 (50.8%)	1000 (50.7%)
Type of speciality			
Vascular	36 (3.6%)	38 (3.9%)	74 (3.8%)
Orthopaedic	785 (79.4%)	779 (79.3%)	1564 (79.4%)
Elderly	168 (17.0%)	165 (16.8%)	333 (16.9%)
Existing grade 2 pressure ulcer			
Yes	59 (6.0%)	54 (5.5%)	113 (5.7%)
No	930 (94.0%)	928 (94.5%)	1858 (94.3%)

Tables 12 and *13* summarise patient baseline characteristics. The median patient age was 76 years (range 55–100 years) and most patients were female (63.9%). There were slightly more female patients allocated to mattress replacements (*n* = 636, 64.8%) than to overlays (*n* = 624, 63.1%). *Tables 14* and *15* summarise baseline clinical details. Two-hundred and fifty-four (12.9%) patients were smokers and 190 (9.6%) patients had diabetes. One-hundred and seventy (8.6%) had lost more than 6 kg in weight during the previous 6 months. The median haemoglobin level on admission was 13.1 g dl^{-1} (range 3.8–19.0 g dl^{-1}).

The presence of skin trauma, a wound or non-blanching erythema (grade 1b) on any site at baseline was considered a potential risk factor for the development of a new pressure ulcer. Wounds included the presence of another chronic wound such as a leg, foot or diabetic ulcer on any site. Details of these factors are provided in *Tables 16* and *17*. A total of 128 (6.5%) patients had skin trauma, 117 (5.9%) patients had a wound and 325 (16.5%) patients had non-blanching erythema on any site at baseline. Slightly more patients in the overlay group (180, 18.2%) had non-blanching erythema (skin grade 1b on any site) at baseline

TABLE 11 *Minimisation details (PP population)*

	Overlay (*n* = 781)	Replacement (*n* = 759)	Total (*n* = 1540)
Type of admission			
Acute	363 (46.5%)	352 (46.4%)	715 (46.4%)
Elective	418 (53.5%)	407 (53.6%)	825 (53.6%)
Type of speciality			
Vascular	32 (4.1%)	29 (3.8%)	61 (4.0%)
Orthopaedic	618 (79.1%)	608 (80.1%)	1226 (79.6%)
Elderly	131 (16.8%)	122 (16.1%)	253 (16.4%)
Existing grade 2 pressure ulcer			
Yes	45 (5.8%)	41 (5.4%)	86 (5.6%)
No	736 (94.2%)	718 (94.6%)	1454 (94.4%)

TABLE 12 *Baseline patient characteristics (ITT population)*

	Overlay (*n* = 989)	Replacement (*n* = 982)	Total (*n* = 1971)
Patient age (years)			
Mean (SD)	75.4 (9.7)	75.0 (9.2)	75.2 (9.5)
Median (range)	76.0 (55.0–100.0)	75.0 (55.0–98.0)	76.0 (55.0–100.0)
Missing	0	0	0
Gender			
Male	365 (36.9%)	346 (35.2%)	711 (36.1%)
Female	624 (63.1%)	636 (64.8%)	1260 (63.9%)

TABLE 13 *Baseline patient characteristics (PP population)*

	Overlay (*n* = 781)	Replacement (*n* = 759)	Total (*n* = 1540)
Patient age (years)			
Mean (SD)	75.2 (9.8)	74.5 (9.3)	74.8 (9.6)
Median (range)	76.0 (55.0–100.0)	75.0 (55.0–98.0)	75.0 (55.0–100.0)
Missing	0	0	0
Gender			
Male	296 (37.9%)	278 (36.6%)	574 (37.3%)
Female	485 (62.1%)	481 (63.4%)	966 (62.7%)

than patients in the replacement group (n = 145, 14.8%).

Tables 18 and *19* summarise the baseline Braden scores. With respect to activity, 1558 (79%) of patients were bedfast, with slightly more patients in the overlay group being bedfast than patients in the replacement group (81.3% compared with 76.8%). In terms of mobility, 1342 (68.1%) patients had very limited mobility and 362 (18.4%) patients were completely immobile; these numbers were similar in the overlay and replacement groups. A majority of the patients had very poor or probably inadequate nutrition, corresponding to 1401 (71.1%) patients. Most patients (n = 1176, 59.7%) had a problem with friction and shear, and 559 (28.4%) patients had a potential problem with friction and shear.

TABLE 14 *Baseline clinical details (ITT population)*

	Overlay (*n* = 989)	**Replacement (*n* = 982)**	**Total (*n* = 1971)**
Smoker			
Yes	131 (13.2%)	123 (12.5%)	254 (12.9%)
No	852 (86.1%)	855 (87.1%)	1707 (86.6%)
Missing	6 (0.6%)	4 (0.4%)	10 (0.5%)
Diabetes			
Yes	88 (8.9%)	102 (10.4%)	190 (9.6%)
No	895 (90.5%)	875 (89.1%)	1770 (89.8%)
Missing	6 (0.6%)	5 (0.5%)	11 (0.6%)
History of weight loss[a]			
Yes	75 (7.6%)	95 (9.7%)	170 (8.6%)
No	904 (91.4%)	881 (89.7%)	1785 (90.6%)
Missing	10 (1.0%)	6 (0.6%)	16 (0.8%)
Haemoglobin (g dl^{-1})[b]			
Mean (SD)	12.9 (1.8)	13.0 (1.7)	12.9 (1.8)
Median (range)	13.1 (3.8–19.0)	13.1 (4.9–18.4)	13.1 (3.8–19.0)
Missing	53	50	103

[a] Weight loss >6 kg (approx. 1 stone) in the past 6 months.
[b] Measured on admission or preoperatively.

TABLE 15 *Baseline clinical details (PP population)*

	Overlay (*n* = 781)	**Replacement (*n* = 759)**	**Total (*n* = 1540)**
Smoker			
Yes	103 (13.2%)	98 (12.9%)	201 (13.1%)
No	677 (86.7%)	661 (87.1%)	1338 (86.9%)
Missing	1 (0.1%)	0 (0%)	1 (0.1%)
Diabetes			
Yes	65 (8.3%)	82 (10.8%)	147 (9.5%)
No	715 (91.5%)	677 (89.2%)	1392 (90.4%)
Missing	1 (0.1%)	0 (0%)	1 (0.1%)
History of weight loss[a]			
Yes	55 (7.0%)	66 (8.7%)	121 (7.9%)
No	722 (92.4%)	692 (91.2%)	1414 (91.8%)
Missing	4 (0.5%)	1 (0.1%)	5 (0.3%)
Haemoglobin (g dl^{-1})[b]			
Mean (SD)	12.9 (1.8)	13.0 (1.7)	13.0 (1.7)
Median (range)	13.1 (3.8–19.0)	13.2 (7.3–18.4)	13.1 (3.8–19.0)
Missing	35	27	62

[a] Weight loss >6 kg (approx. 1 stone) in the past 6 months.
[b] Measured on admission or preoperatively.

TABLE 16 *Presence of skin trauma, wound or non-blanching erythema at baseline (ITT population)*[a]

	Overlay (*n* = 989)	Replacement (*n* = 982)	Total (*n* = 1971)
Skin trauma			
Yes	64 (6.5%)	64 (6.5%)	128 (6.5%)
No	925 (93.5%)	918 (93.5%)	1843 (93.5%)
Wound			
Yes	57 (5.8%)	60 (6.1%)	117 (5.9%)
No	932 (94.2%)	922 (93.9%)	1854 (94.1%)
Non-blanching erythema (grade 1b)			
Yes	180 (18.2%)	145 (14.8%)	325 (16.5%)
No	809 (81.8%)	837 (85.2%)	1646 (83.5%)

[a] The presence of skin trauma, a wound or non-blanching erythema on one or more sites at the baseline skin assessment. Wounds include sites classified as a wound from skin grade and comments and also the presence of other existing chronic wounds (e.g. leg, foot or diabetic ulcer).

TABLE 17 *Presence of skin trauma, wound or non-blanching erythema at baseline (PP population)*[a]

	Overlay (*n* = 781)	Replacement (*n* = 759)	Total (*n* = 1540)
Skin trauma			
Yes	49 (6.3%)	51 (6.7%)	100 (6.5%)
No	732 (93.7%)	708 (93.3%)	1440 (93.5%)
Wound			
Yes	51 (6.5%)	40 (5.3%)	91 (5.9%)
No	730 (93.5%)	719 (94.7%)	1449 (94.1%)
Non-blanching erythema (grade 1b)			
Yes	133 (17.0%)	109 (14.4%)	242 (15.7%)
No	648 (83.0%)	650 (85.6%)	1298 (84.3%)

[a] The presence of skin trauma, a wound or non-blanching erythema on one or more sites at the baseline skin assessment. Wounds include sites classified as a wound from skin grade and comments and also the presence of other existing chronic wounds (e.g. leg, foot or diabetic ulcer).

Primary end-point

The primary end-point was whether or not a patient developed a new grade 2 or above pressure ulcer on any site after the baseline skin assessment and before trial completion. Sites with a skin grade 2 or above, or a wound or bandage/dressing *in situ* at baseline, were excluded from the primary end-point analysis.

ITT population

Table 20 summarises the analysis of the proportions of patients developing a new pressure ulcer. A total of 106 (10.7%) patients in the overlay group and 101 (10.3%) patients in the replacement group developed one or more new grade 2 pressure ulcers. A χ^2 test was used to compare the two mattress groups; the difference in the proportions of patients with a new pressure ulcer (overlay – replacement) was 0.4% (95% CI –2.3 to 3.1%), which was not statistically significant [$\chi^2 = 0.1$ on one degree of freedom (1 df), $p = 0.75$]. The 95% confidence interval indicates that the true difference could range from overlay patients having a lower incidence to overlay patients having a higher incidence of new pressure ulcers.

Some patients developed more than one new pressure ulcer; further details of all new pressure ulcers are summarised in *Table 21*. There was a total of 305 new pressure ulcers in 207 patients.

TABLE 18 *Baseline Braden scores (ITT population)*[a]

	Overlay (*n* = 989)	Replacement (*n* = 982)	Total (*n* = 1971)
Sensory perception			
Completely limited	5 (0.5%)	3 (0.3%)	8 (0.4%)
Very limited	28 (2.8%)	34 (3.5%)	62 (3.1%)
Slightly limited	214 (21.6%)	219 (22.3%)	433 (22.0%)
No impairment	716 (72.4%)	700 (71.3%)	1416 (71.8%)
Missing	26 (2.6%)	26 (2.6%)	52 (2.6%)
Moisture			
Completely moist	23 (2.3%)	21 (2.1%)	44 (2.2%)
Very moist	130 (13.1%)	126 (12.8%)	256 (13.0%)
Occasionally moist	457 (46.2%)	457 (46.5%)	914 (46.4%)
Rarely moist	344 (34.8%)	345 (35.1%)	689 (35.0%)
Missing	35 (3.5%)	33 (3.4%)	68 (3.5%)
Activity			
Bedfast	804 (81.3%)	754 (76.8%)	1558 (79.0%)
Chairfast	87 (8.8%)	124 (12.6%)	211 (10.7%)
Walks occasionally	20 (2.0%)	31 (3.2%)	51 (2.6%)
Walks frequently	52 (5.3%)	49 (5.0%)	101 (5.1%)
Missing	26 (2.6%)	24 (2.4%)	50 (2.5%)
Mobility			
Completely immobile	185 (18.7%)	177 (18.0%)	362 (18.4%)
Very limited	676 (68.4%)	666 (67.8%)	1342 (68.1%)
Slightly limited	46 (4.7%)	56 (5.7%)	102 (5.2%)
No limitation	56 (5.7%)	58 (5.9%)	114 (5.8%)
Missing	26 (2.6%)	25 (2.5%)	51 (2.6%)
Nutrition			
Very poor	403 (40.7%)	371 (37.8%)	774 (39.3%)
Probably inadequate	304 (30.7%)	323 (32.9%)	627 (31.8%)
Adequate	185 (18.7%)	196 (20.0%)	381 (19.3%)
Excellent	71 (7.2%)	67 (6.8%)	138 (7.0%)
Missing	26 (2.6%)	25 (2.5%)	51 (2.6%)
Friction and shear			
Problem	604 (61.1%)	572 (58.2%)	1176 (59.7%)
Potential problems	271 (27.4%)	288 (29.3%)	559 (28.4%)
No apparent problems	88 (8.9%)	98 (10.0%)	186 (9.4%)
Missing	26 (2.6%)	24 (2.4%)	50 (2.5%)

[a] Recorded at the time of mattress allocation.

There was little difference between the mattress groups, with 156 (51.1% of the total number of new ulcers) occurring in the overlay group and 149 (48.9%) in the replacement group. Most new ulcers (n = 128, 41.9%) developed on the buttocks and 69 (22%) developed on the sacrum. For ulcers that developed on sites other than those specified on the case-record forms (i.e. sacrum, buttocks, heels and hips), the most common site was the elbows [34 (11.1%) ulcers developed on either the left or right elbow].

Table 22 summarises the numbers of patients developing a new pressure ulcer, by the minimisation factors. More acute patients (n = 172, 17.7%) developed a new pressure ulcer compared with elective patients (n = 35, 3.5%). Elderly patients were more likely to develop a new pressure ulcer, with 57 (17.1%) elderly patients developing an ulcer, compared with nine (12.2%) vascular and 141 (9.0%) orthopaedic patients. Overall, 20 (17.7%) patients with an existing grade 2 ulcer at randomisation developed a new ulcer,

TABLE 19 *Baseline Braden scores (PP population)*[a]

	Overlay (*n* = 781)	Replacement (*n* = 759)	Total (*n* = 1540)
Sensory perception			
Completely limited	4 (0.5%)	2 (0.3%)	6 (0.4%)
Very limited	19 (2.4%)	28 (3.7%)	47 (3.1%)
Slightly limited	182 (23.3%)	163 (21.5%)	345 (22.4%)
No impairment	572 (73.2%)	561 (73.9%)	1133 (73.6%)
Missing	4 (0.5%)	5 (0.7%)	9 (0.6%)
Moisture			
Completely moist	16 (2.0%)	15 (2.0%)	31 (2.0%)
Very moist	103 (13.2%)	98 (12.9%)	201 (13.1%)
Occasionally moist	366 (46.9%)	370 (48.7%)	736 (47.8%)
Rarely moist	285 (36.5%)	265 (34.9%)	550 (35.7%)
Missing	11 (1.4%)	11 (1.4%)	22 (1.4%)
Activity			
Bedfast	644 (82.5%)	578 (76.2%)	1222 (79.4%)
Chairfast	72 (9.2%)	103 (13.6%)	175 (11.4%)
Walks occasionally	17 (2.2%)	29 (3.8%)	46 (3.0%)
Walks frequently	44 (5.6%)	45 (5.9%)	89 (5.8%)
Missing	4 (0.5%)	4 (0.5%)	8 (0.5%)
Mobility			
Completely immobile	150 (19.2%)	145 (19.1%)	295 (19.2%)
Very limited	543 (69.5%)	509 (67.1%)	1052 (68.3%)
Slightly limited	38 (4.9%)	50 (6.6%)	88 (5.7%)
No limitation	46 (5.9%)	51 (6.7%)	97 (6.3%)
Missing	4 (0.5%)	4 (0.5%)	8 (0.5%)
Nutrition			
Very poor	305 (39.1%)	301 (39.7%)	606 (39.4%)
Probably inadequate	242 (31.0%)	250 (32.9%)	492 (31.9%)
Adequate	165 (21.1%)	146 (19.2%)	311 (20.2%)
Excellent	65 (8.3%)	58 (7.6%)	123 (8.0%)
Missing	4 (0.5%)	4 (0.5%)	8 (0.5%)
Friction and shear			
Problem	477 (61.1%)	461 (60.7%)	938 (60.9%)
Potential problems	222 (28.4%)	208 (27.4%)	430 (27.9%)
No apparent problems	78 (10.0%)	86 (11.3%)	164 (10.6%)
Missing	4 (0.5%)	4 (0.5%)	8 (0.5%)

[a] Recorded at the time of mattress allocation.

TABLE 20 *Primary analysis: proportion of patients developing a new pressure ulcer*

	Overlay (%)	Replacement (%)	Difference (95% CI)	χ^2	*p*
ITT population (*n* = 1971)	10.7	10.3	0.4 (–2.3 to 3.1)	0.10	0.75
PP population (*n* = 1540)	7.6	8.3	–0.7 (–3.4 to 2.0)	0.29	0.59
Sensitivity analysis (*n* = 1963)	10.6	10.2	0.4 (–2.3 to 3.1)	0.08	0.78

TABLE 21 *Primary end-point: development of a new pressure ulcer (ITT population)*

	Overlay (*n* = 989)	Replacement (*n* = 982)	Total (*n* = 1971)
Developed one or more new grade 2 pressure ulcers	106 (10.7%)	101 (10.3%)	207 (10.5%)
Number of new pressure ulcers per patient			
1	76 (71.7%)	70 (69.3%)	146 (70.5%)
2	17 (16.0%)	19 (18.8%)	36 (17.4%)
3	8 (7.5%)	7 (6.9%)	15 (7.2%)
4	3 (2.8%)	5 (5.0%)	8 (3.9%)
5	2 (1.9%)	0 (0%)	2 (1.0%)
Total number of new ulcers (% of total)	156 (51.1%)	149 (48.9%)	305
Location of new pressure ulcers (% of total number of new ulcers)			
Sacrum	31 (19.9%)	38 (25.5%)	69 (22.6%)
Buttocks	58 (37.8%)	70 (46.9%)	129 (42.3%)
Heels	21 (13.5%)	21 (14.1%)	42 (13.8%)
Hips	3 (1.9%)	1 (0.7%)	4 (1.9%)
Other[a]	42 (26.9%)	19 (12.8%)	61 (20%)
[a]Location of other sites			
Elbow	23 (14.7%)	11 (7.4%)	34 (11.1%)
Ankle	5 (3.2%)	2 (1.3%)	7 (2.3%)
Buttock	1 (0.6%)	0 (0%)	1 (0.3%)
Head	1 (0.6%)	0 (0%)	1 (0.3%)
Foot	1 (0.6%)	0 (0%)	1 (0.3%)
Lower leg	2 (1.3%)	0 (0%)	2 (0.7%)
Leg	4 (2.6%)	3 (2.0%)	7 (2.3%)
Back	6 (3.8%)	1 (0.7%)	7 (2.3%)
Miscellaneous	0 (0%)	2 (1.3%)	2 (0.7%)

TABLE 22 *Development of a new pressure ulcer by minimisation factors (ITT population)*

	Overlay (*n* = 989)	Replacement (*n* = 982)	Total (*n* = 1971)
Type of admission			
Acute	88/488 (18.0%)	84/483 (17.4%)	172/971 (17.7%)
Elective	18/501 (3.6%)	17/499 (3.4%)	35/1000 (3.5%)
Type of speciality			
Vascular	3/36 (8.3%)	6/38 (15.8%)	9/74 (12.2%)
Orthopaedic	75/785 (9.6%)	66/779 (8.5%)	141/1564 (9.0%)
Elderly	28/168 (16.7%)	29/165 (17.6%)	57/333 (17.1%)
Existing grade 2 pressure ulcer			
Yes	10/59 (16.9%)	10/54 (18.5%)	20/113 (17.7%)
No	96/930 (10.3%)	91/928 (9.8%)	187/1858 (10.1%)

compared with 187 (10.1%) patients who had no pre-existing ulcers.

PP population

In the PP population 59 (7.6%) patients in the overlay group and 63 (8.3%) patients in the replacement group developed a new pressure ulcer (*Table 23*). The results from the χ^2 test gave a p-value of 0.59 and a difference in proportions (overlay – replacement) of –0.7% (95% CI –3.4 to 2.0). There was a total of 180 new pressure ulcers in 122 patients. More new ulcers developed in the

replacement group than in the overlay group, with 100 (55.6% of the total number of new ulcers) new ulcers occurring in the replacement group compared with 80 (44.4%) in the overlay group. *Table 23* provides further details of the numbers of new pressure ulcers per patient and their locations.

Sensitivity analysis

A sensitivity analysis was conducted to assess the effect on the primary ITT results of including patients who did not satisfy the trial eligibility criteria. This patient population excluded the four patients who did not satisfy the eligibility criteria and a further four patients who had a skin grade 3 or above recorded at the baseline skin assessment. For the four patients with a grade 3 or above at baseline, one patient had a grade 3 on the buttocks which was not present at the eligibility assessment, one patient had a grade 4 on their left hip which was a surgical wound, one patient had a grade 4 on the left heel which was a diabetic ulcer to be amputated and one patient had a grade 5 on their right heel which was described as ischaemic damage. The results from the χ^2 test gave a p-value of 0.78 and a difference in proportions (overlay – replacement) of 0.4% (95% CI –2.3 to 3.1%).

The PP analysis and sensitivity analysis results are consistent with the ITT results and confirm that there were no statistically significant differences between the mattress groups in the proportions of patients who developed a new pressure ulcer.

Adjusted analysis

Table 24 summarises the results of the adjusted analysis of the primary end-point. A logistic regression model was used to adjust for the minimisation factors and prespecified baseline covariates (as detailed in the methods section). Small centres (those with fewer than 50 patients) were combined to prevent model convergence problems. The baseline Braden mobility score was not included in the model as it was correlated with the Braden activity score. In the adjusted analysis the p-value for the mattress group was 0.7, confirming the conclusions from the unadjusted analysis. The odds ratio (OR) for developing a new pressure ulcer on the overlay compared with the replacement mattress was 0.94 (95% CI 0.68 to 1.29), indicating no difference between the mattresses with respect to the odds of developing a new pressure ulcer.

The type of admission had a highly significant effect on the proportion developing a new pressure ulcer ($p < 0.0001$), with the odds of developing an ulcer for an acute patient being more than three times those of an elective patient (OR 3.65, 95% CI 2.27 to 5.85). The presence of a wound, skin trauma or non-blanching erythema on any site at baseline were also statistically significant risk factors. The odds of developing a new pressure ulcer for a patient with a baseline wound were three times those for a patient without a wound (OR 2.96, 95% CI 1.73 to 5.08, $p < 0.0001$). For patients with skin trauma the odds of developing a new pressure ulcer were approximately 1.7 times those of a patient without skin trauma (OR 1.67, 95% CI 1.00 to 2.80, $p = 0.05$). Patients with non-blanching erythema were almost twice as likely as patients without non-blanching erythema to develop a pressure ulcer (OR 1.95, 95% CI 1.31 to 2.91, $p = 0.001$).

Patient age ($p = 0.03$) and haemoglobin concentration on admission ($p = 0.01$) were also statistically significant risk factors for the development of a new pressure ulcer. The odds of developing a new pressure ulcer increased with increasing age (OR 1.02, 95% CI 1.002 to 1.04), indicating a 2% increase in the odds of pressure ulcer development for an increase in patient age of 1 year. The odds of developing a new pressure ulcer decreased with an increase in haemoglobin on admission (OR 0.89, 95% CI 0.82 to 0.97), indicating an 11% reduction in the odds of pressure ulcer development for an increase in baseline haemoglobin of 1 g dl^{-1}. Diabetes was also a statistically significant risk factor ($p = 0.047$), with the odds of developing a new pressure ulcer for a person with diabetes being 1.6 times those for a person without diabetes (OR 1.61, 95% CI 1.007 to 2.56). Centre had a statistically significant effect on the likelihood of developing a new ulcer ($p = 0.02$), indicating differences between centres in the proportions of patients developing new ulcers. However, when a mattress by centre interaction term was included in the model this was not significant (χ^2 test statistic of 4.2, 7 df, $p = 0.76$), indicating that any differences between mattresses were similar across the centres.

Time to new pressure ulcer development

Figure 5(a, b) shows Kaplan–Meier curves of the time to develop a new pressure ulcer, for the ITT and PP populations. The log-rank test was used to compare time to new pressure ulcer development. No statistically significant differences between the

TABLE 23 *Primary end-point: development of a new pressure ulcer (PP population)*

	Overlay (*n* = 781)	**Replacement (*n* = 759)**	**Total (*n* = 1540)**
Developed one or more new grade 2 pressure ulcers	59 (7.6%)	63 (8.3%)	122 (7.9%)
Number of new pressure ulcers per patient			
1	44 (74.6%)	40 (63.5%)	84 (68.9%)
2	11 (18.6%)	13 (20.6%)	24 (19.7%)
3	3 (5.1%)	6 (9.5%)	9 (7.4%)
4	0 (0%)	4 (6.3%)	4 (3.3%)
5	1 (1.7%)	0 (0%)	1 (0.8%)
Total number of new ulcers (% of total)	80 (44.4%)	100 (55.6%)	180
Location of new pressure ulcers (% of total number of new ulcers)			
Sacrum	13 (16.3%)	23 (23.0%)	36 (20.0%)
Buttocks	27 (33.8%)	47 (47.0%)	74 (41.1%)
Heels	13 (16.3%)	14 (14.0%)	27 (15.0%)
Hips	3 (3.8%)	1 (1.0%)	4 (2.2%)
Other[a]	24 (30.0%)	15 (15.0%)	39 (21.7%)
[a]Location of other sites			
Elbow	11 (13.8%)	6 (6.0%)	17 (9.4%)
Ankle	4 (5.0%)	2 (2.0%)	6 (3.3%)
Sacrum	0 (0%)	2 (2.0%)	2 (1.1%)
Foot	1 (1.3%)	0 (2.0%)	1 (0.6%)
Lower leg	1 (1.3%)	0 (2.0%)	1 (0.6%)
Leg	2 (2.5%)	2 (2.0%)	4 (2.2%)
Back	5 (6.3%)	1 (1.0%)	6 (3.3%)
Miscellaneous	0 (0%)	2 (2.0%)	2 (1.1%)

TABLE 24 *Adjusted analysis of the primary end-point*

Model parameter	***p***	**OR (95% CI)**
Mattress (overlay: replacement)	0.70	0.94 (0.68 to 1.29)
Centre[a]	0.02	
Admission[a] (acute: elective)	<0.0001	3.65 (2.27 to 5.85)
Speciality[a] (vascular: elderly)	0.54	1.31 (0.51 to 3.33)
(orthopaedic: elderly)		1.28 (0.82 to 2.01)
Existing pressure ulcer[a] (yes: no)	0.92	0.97 (0.52 to 1.79)
Baseline wound (yes: no)	<0.0001	2.96 (1.73 to 5.08)
Baseline skin trauma (yes: no)	0.05	1.67 (0.999 to 2.80)
Baseline grade 1b (yes: no)	0.001	1.95 (1.31 to 2.91)
Age (years)	0.03	1.02 (1.002 to 1.04)
Diabetes (yes: no)	0.047	1.61 (1.007 to 2.56)
Braden activity (bedfast: walks frequently)	0.22	0.70 (0.19 to 2.59)
(chairfast: walks frequently)		0.36 (0.09 to 1.52)
(walks occasionally: walks frequently)		0.91 (0.16 to 5.08)
Braden nutrition (very poor or inadequate: adequate or excellent)	0.28	1.31 (0.81 to 2.13)
Haemoglobin on admission/preoperatively (g dl^{-1})	0.01	0.89 (0.82 to 0.97)

[a] Minimisation factors.
Small centres ($n < 50$) were combined for analysis purposes to prevent model convergence problems. Combined centres consisted of Leeds Seacroft ($n = 13$), Hartlepool ($n = 22$) and Leeds Chapel Allerton Hospital ($n = 40$).
A mattress by centre interaction term was assessed for inclusion in the model; this was not statistically significant (χ^2 test statistic of 4.2 on 7 df, $p = 0.76$).

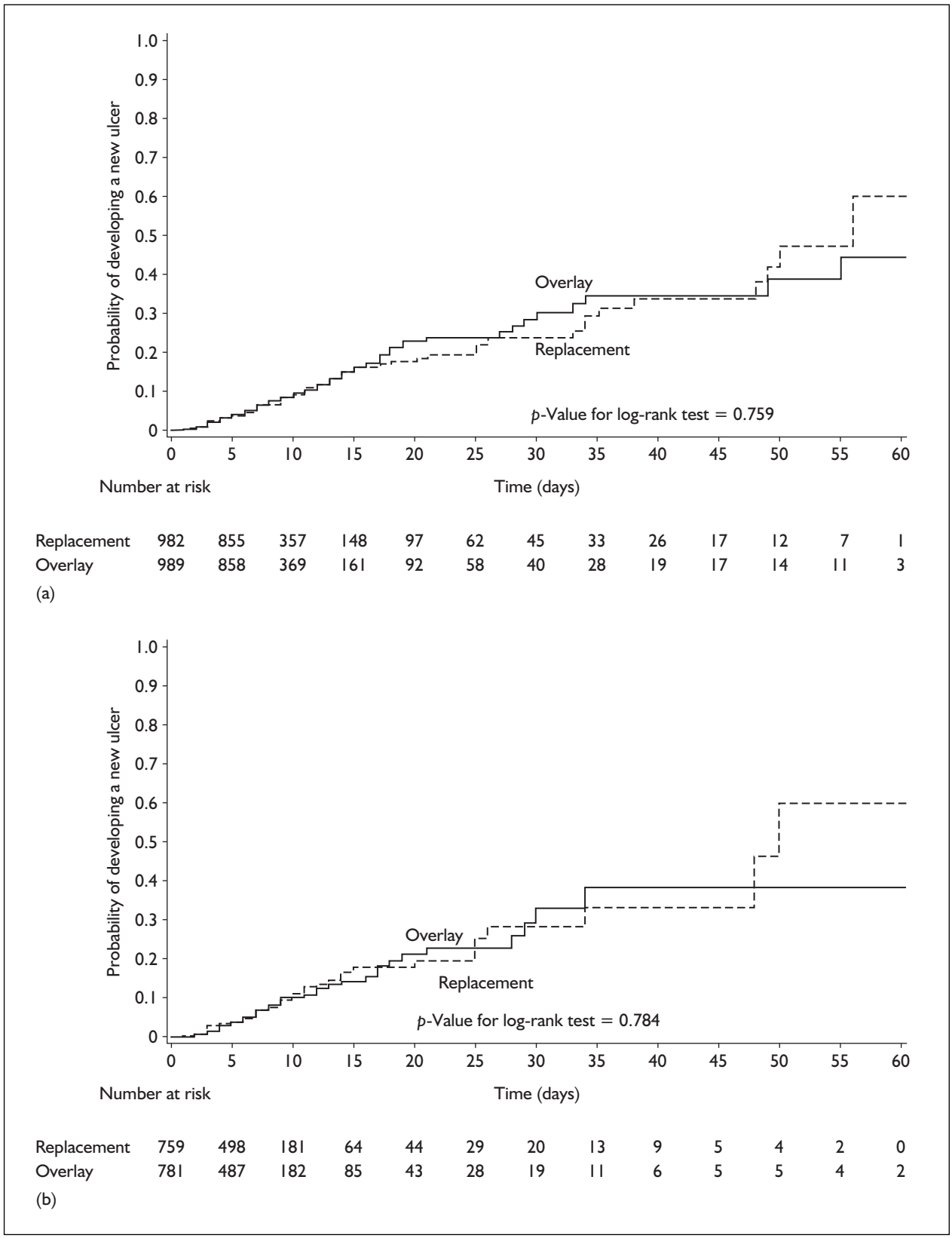

FIGURE 5 *Kaplan–Meier plots of the time to the development of a new pressure ulcer: (a) ITT population; (b) PP population*

TABLE 25 *The development of a new pressure ulcer within 30 days*

	Overlay	Replacement	Total	Difference (95% CI)	χ^2	*p*
ITT population	99/989 (10.0%)	91/982 (9.3%)	190/1971 (9.6%)	0.7 (–1.9 to 3.3)	0.31	0.58
PP population	56/781 (7.2%)	59/759 (7.8%)	115/1540 (7.5%)	–0.6 (–3.2 to 2.0)	0.20	0.65

TABLE 26 *Maximum grade of new pressure ulcers*

	Overlay	Replacement	Total
Number of new ulcers (ITT population)	156	149	305
Maximum grade			
2	153 (98.1%)	144 (96.6%)	297 (97.4%)
3	3 (1.9%)	5 (3.4%)	8 (2.6%)
Number of new ulcers (PP population)	80	100	180
Maximum grade			
2	78 (97.5%)	98 (98.0%)	176 (97.8%)
3	2 (2.5%)	2 (2.0%)	4 (2.2%)

Patients may have more than one new pressure ulcer; summary table is for all new ulcers.

mattress groups were found for either the ITT population (log-rank test statistic 0.094, $p = 0.76$) or the PP population (log-rank test statistic 0.075, $p = 0.78$). As there were few events, the Kaplan–Meier estimates of the median time to development of a new pressure ulcer (the estimate of the time at which 50% of patients would have a new pressure ulcer) may not be reliable as the median survival time was not reached for the overlay group for the ITT or PP analyses. For the ITT population the Kaplan–Meier estimate of the median time to a new pressure ulcer was 56 days (95% CI 48 days, upper limit not estimable) for the replacement group and it was not reached for the overlay group. For the PP population the Kaplan–Meier estimate of the median time to a new pressure ulcer was 50 days (95% CI 48 days, upper limit not estimable) for the replacement group and it was not reached for the overlay group.

Development of a new pressure ulcer within 30 days

Table 25 summarises the numbers of patients who developed a new pressure ulcer within 30 days of randomisation. A total of 99 (10%) overlay and 91 (9.3%) replacement patients developed a new ulcer within 30 days, for the ITT population. Using a χ^2 test this difference was not statistically significant ($\chi^2 = 0.31$, $p = 0.58$). There was also no significant difference ($\chi^2 = 0.2$, $p = 0.65$) between the mattress groups for the PP population.

Maximum grade and surface area of new pressure ulcers

Table 26 summarises the maximum grade of new pressure ulcers on a per ulcer basis. The planned statistical analysis comparing the difference in maximum ulcer grades between the mattress groups has not been performed as most new ulcers ($n = 297$, 97.4%) reached a maximum grade of 2. Three (1.9%) new ulcers in the overlay group and 5 (3.4%) in the replacement group reached a maximum grade of 3.

Table 27 provides details of the maximum surface area of all new ulcers on a per-patient basis. If a patient developed one or more new pressure ulcers during the trial then the total area of all new ulcers, at each assessment, was obtained from the tracing measurements. The largest value for each patient has been summarised and used in the analysis. The total ulcer areas were similar for the overlay and replacement groups, with most new ulcers being small. The overall median area was 1.1 cm^2, implying that 50% of the patients with a new ulcer had a total area of new ulceration that was less than 1 cm^2. The median total area for the ITT population was 1.2 cm^2 (range 0.1–40.9 cm^2) for the overlay group and 1.1 cm^2 (range 0.1–68.1 cm^2) for the replacement group. The patients with the large total areas of 40.9 cm^2 and 68.1 cm^2 each had an ulcer that had spread over the sacrum and buttocks. As the total new ulcer areas were not normally distributed, the Mann–Whitney *U*-test was used to compare the

TABLE 27 *Maximum total surface area of new ulcers per patient*

	Overlay	Replacement	Total
Maximum ulcer area (cm^2) (ITT)			
Mean (SD)	3.8 (7.4)	3.6 (8.3)	3.7 (7.8)
Median (range)	1.2 (0.1–40.9)	1.1 (0.1–68.1)	1.1 (0.1–68.1)
Unable to trace ulcer	16	12	28
Number of patients	90	89	179
Maximum ulcer area (cm^2) (PP)			
Mean (SD)	4.2 (7.2)	4.0 (9.7)	4.1 (8.6)
Median (range)	2.0 (0.1–37.3)	1.1 (0.1–68.1)	1.5 (0.1–68.1)
Unable to trace ulcer	9	8	17
Number of patients	50	55	105

The total area of all new areas of ulceration for each patient, at each skin assessment was obtained from the tracing measurements. The largest area reached per patient has been summarised.

total surface area of new ulcers; there was no evidence of a difference between the mattress groups for the ITT population ($\chi^2 = 0.0005$, $p = 0.98$) or the PP population ($\chi^2 = 0.395$, $p = 0.53$).

Subgroup analyses

Forty-two new ulcers developed on the heels in 37 patients (18 overlay and 19 replacement). Owing to the small number of patients who developed an ulcer on the heels, the planned subgroup analysis to investigate whether there was any difference in the mattress effect between patients with a new pressure ulcer on the heels, compared with patients with a new pressure ulcer on the torso, was not performed. For risk level, patients with an existing pressure ulcer were considered 'high risk' and patients without an existing ulcer were considered 'at risk'. The inclusion of the interaction term between risk level and mattress in a logistic regression model was not statistically significant ($\chi^2 = 0.1$, 1 df, $p = 0.75$). This indicates that there was no evidence of a difference in the mattress effect on the proportion developing a new pressure ulcer, between patients at different ulcer risk levels.

Mattress compliance

Mattress received at baseline

Table 28 summarises the actual mattress each patient received at baseline, by randomised mattress group. Not all patients were placed on the randomised mattress at baseline. The numbers of patients who were placed on the correct mattress at baseline were similar in each mattress group, with 818 (82.7%) patients randomised to overlay receiving a trial or equivalent overlay mattress and 804 (81.9%) patients randomised to replacement receiving a trial or equivalent replacement mattress. Further details of the reasons for receiving a different mattress are provided in *Table 28*. Most patients ($n = 151$, 43.3%) were not placed on the randomised mattress because it was unavailable and 66 (18.9%) had already been allocated another mattress.

Some patients were placed on the mattress from the opposing treatment group, with 87 (8.8%) patients randomised to overlay receiving a replacement mattress and 111 (11.3%) patients randomised to replacement receiving an overlay mattress.

More patients randomised to overlay ($n = 10$, 6.8%) were not placed on the randomised mattress because of a clinical decision than patients randomised to replacement ($n = 2$, 1.1%). For the ten patients who were not put on an overlay because of a clinical decision, nine received a replacement and one patient received a foam mattress. For the two patients not put on replacement owing to a clinical decision, one received an overlay and one patient was placed on a foam mattress. There was some evidence of a nurse preference, as two patients in one centre were randomised to overlay but placed on a replacement mattress as the nurses were "unhappy to nurse patient on the randomised mattress". Another patient randomised to overlay was given a replacement as they were assessed as 'high risk'.

TABLE 28 *Baseline mattress provision (ITT population)*

	Randomised mattress		
	Overlay (*n* = 989)	**Replacement (*n* = 982)**	**Total (*n* = 1971)**
Mattress as randomised			
Yes	818 (82.7%)	804 (81.9%)	1622 (82.3%)
No	171 (17.3%)	178 (18.1%)	349 (17.7%)
If no, reason mattress not as randomised (% of not as randomised)			
Accidental/reason not stated	20 (11.7%)	17 (9.6%)	37 (10.6%)
Unavailable	66 (38.6%)	85 (47.8%)	151 (43.3%)
Clinical decision	10 (5.8%)	2 (1.1%)	12 (3.4%)
Theatre organisation	19 (11.1%)	11 (6.2%)	30 (8.6%)
Technical fault	0 (0.0%)	2 (1.1%)	2 (0.6%)
Already allocated another mattress	31 (18.1%)	35 (19.7%)	66 (18.9%)
Surgery cancelled	6 (3.5%)	11 (6.2%)	17 (4.9%)
Withdrawn or discharged before mattress provision	8 (4.7%)	6 (3.4%)	14 (4.0%)
Missing data	11 (6.4%)	9 (5.1%)	20 (5.7%)
Actual mattress received			
Overlay[a]	818 (82.7%)	111 (11.3%)	929 (47.1%)
Replacement[a]	87 (8.8%)	804 (81.8%)	891 (45.2%)
Foam	26 (2.6%)	35 (3.6%)	61 (3.1%)
Other non-trial	32 (3.2%)	7 (0.7%)	39 (2.0%)
No details given	26 (2.6%)	25 (2.5%)	51 (2.6%)

[a] Trial or equivalent mattress.

TABLE 29 *Mattress changes (ITT population)*

	Randomised mattress		
	Overlay (*n* = 989)	**Replacement (*n* = 982)**	**Total (*n* = 1971)**
Number of patients with one or more mattress changes	375 (37.9%)	326 (33.2%)	701 (35.6%)
Number of changes per patient			
1	346 (35.0%)	290 (29.5%)	636 (32.3%)
2	20 (2.0%)	28 (2.9%)	48 (2.4%)
3	9 (0.9%)	4 (0.4%)	13 (0.7%)
4	0 (0%)	2 (0.2%)	2 (0.1%)
5	0 (0%)	1 (0.1%)	1 (0.1%)
Reason for mattress change *n* (% of all mattress changes)			
Patient request	232 (56.2%)	185 (49.9%)	417 (53.2%)
Ward led	180 (43.6%)	184 (49.6%)	364 (46.4%)
Reason not given	1 (0.2%)	2 (0.5%)	3 (0.4%)

Mattress changes

During the trial period, patients could change mattresses, either at their own request or because of a ward-led decision. Details of the numbers of patients who changed mattresses, the number of changes per patient and the reason for each change are presented in *Table 29*. Mattress changes where the reason was given as 'mattress no longer required' have not been counted as a mattress change for the mattress change summaries. During the trial, 701 (35.6%) patients had at least one mattress change, corresponding to 375 (37.9%) patients allocated overlays and 326 (33.2%) patients allocated replacements. Most patients (n = 636, 32.3%) only had one mattress change, with 29 (2.9%) overlay patients and

TABLE 30 *Mattress changes: patients with an existing grade 2 pressure ulcer*

	Randomised mattress		
	Overlay (*n* = 59)	**Replacement (*n* = 54)**	**Total (*n* = 113)**
Number of patients with one or more mattress changes	15 (25.4%)	14 (25.9%)	29 (25.7%)
Number of changes per patient			
1	13 (22.0%)	10 (18.5%)	23 (20.3%)
2	2 (3.4%)	3 (5.6%)	5 (4.4%)
3	0 (0%)	1 (1.9%)	1 (0.9%)
Reason for mattress change *n* (% of all mattress changes)			
Patient request	4 (23.5%)	4 (21.1%)	8 (22.2%)
Ward led	13 (76.5%)	15 (78.9%)	28 (77.8%)

35 (3.6%) replacement patients having two or more changes. One patient randomised to replacement changed mattresses five times during the trial, with four of these changes being because of a ward transfer. More changes (53.2% of all mattress changes) were at the patient's request as opposed to ward led (46.4% of all mattress changes).

Table 30 presents the same mattress change information, for patients with an existing grade 2 pressure ulcer at the baseline assessment. Patients with an existing pressure ulcer had a lower incidence of mattress changes, with 15 (25.4%) patients in the overlay group and 14 (25.9%) patients in the replacement group having one or more mattress changes during the trial. For patients with an existing ulcer, most mattress changes (77.8% of all mattress changes) were ward led.

Further details of the first mattress change for each patient are presented in *Tables 31* and *32*. *Table 31* summarises the first mattress change for ward-led changes and *Table 32* summarises the first mattress change for patient-requested changes. Three patients (one overlay and two replacement) did not provide a reason for their mattress change and are not summarised in these tables; however, all three changed to a foam mattress. More first mattress changes were at the patient's request, with 225 (22.8%) patients in the overlay group and 182 (18.5%) patients in the replacement group requesting a mattress change. For changes that were ward led, 149 (15.1%) patients in the overlay group and 142 (14.5%) patients in the replacement group had an initial change that was ward led. The median time to the first mattress change was 3 days (range 0–34 days) for patient-requested changes and 4 days (range 0–47 days) for ward-led changes.

The reasons for the first ward-led change are summarised in *Table 31*. Twenty-three patients (15 overlay and eight replacement) were moved onto the randomised mattress, as it had become available. These patients were classed as having a mattress change, rather than a delay in receiving the randomised mattress, as no information on the actual time of the mattress change was collected. More patients in the overlay group (n = 29, 19.5%) had their mattresses changed because of a clinical decision compared with patients in the replacement group (n = 22, 15.5%). Of these patients, 11 overlay patients were changed to a replacement mattress, with nine patients having comments from the CRN that the change was due to the patient's general condition, and only one replacement patient was changed to an overlay mattress. More patients in the replacement group (n = 21, 14.8%) than in the overlay group (n = 10, 6.7%) had a ward-led change in order to give the mattress to another patient. Overall, slightly more patients in the overlay group (n = 27, 7.2%) changed to a replacement mattress in comparison with those in the replacement group (n = 17, 5.2%) who changed to an overlay mattress.

Effect of mattress changes on the primary end-point

As this was a pragmatic trial, the ITT analysis is the primary analysis. However, the considerable numbers of patients who changed mattresses during the trial period may affect this result. The ITT result provides information that relates to usual mattress policies and is the most applicable to the clinical setting. The PP analysis was an 'as-

TABLE 31 *Details of the first mattress change: ward-led changes (ITT population)*

	Randomised mattress		
	Overlay (*n* = 989)	**Replacement (*n* = 982)**	**Total (*n* = 1971)**
Number of patients with an initial ward-led change	149 (15.1%)	142 (14.5%)	291 (14.8%)
Time to first change (days)			
Mean (SD)	6.3 (7.8)	7.2 (8.8)	6.7 (8.3)
Median (range)	4.0 (0.0–47.0)	4.0 (0.0–46.0)	4.0 (0.0–47.0)
Missing	0	0	0
Mattress type changed to			
Overlay	15 (10.1%)	16 (11.3%)	31 (10.6%)
Replacement	24 (16.1%)	12 (8.5%)	36 (12.3%)
Foam	91 (61.1%)	101 (71.1%)	192 (66.0%)
Other non-trial	17 (11.4%)	13 (9.2%)	30 (10.3%)
Mattress details not given	2 (1.3%)	0 (0%)	2 (0.7%)
Reason for ward-led change			
Clinical decision	29 (19.5%)	22 (15.5%)	51 (17.5%)
Technical fault	20 (13.4%)	23 (16.2%)	43 (14.8%)
Required by another patient	10 (6.7%)	21 (14.8%)	31 (10.6%)
Ward transfer	39 (26.3%)	36 (25.4%)	75 (25.8%)
Patient safety/health	4 (2.6%)	6 (4.2%)	10 (3.4%)
Unknown	9 (6.0%)	6 (4.2%)	15 (5.2%)
Randomised mattress now available	15 (10.0%)	8 (5.6%)	23 (7.9%)
Rehabilitation	23 (15.4%)	20 (14.1%)	43 (14.8%)

TABLE 32 *Details of the first mattress change: patient-requested changes (ITT population)*

	Randomised mattress		
	Overlay (*n* = 989)	**Replacement (*n* = 982)**	**Total (*n* = 1971)**
Number of patients with an initial patient-requested change	225 (22.8%)	182 (18.5%)	407 (20.6%)
Time to first change (days)			
Mean (SD)	3.2 (3.0)	3.8 (3.3)	3.5 (3.2)
Median (range)	3.0 (0.0–34.0)	3.0 (0.0–25.0)	3.0 (0.0–34.0)
Missing	0	0	0
n	225	182	407
Mattress type changed to			
Overlay	0 (0%)	1 (0.5%)	1 (0.2%)
Replacement	3 (1.3%)	1 (0.5%)	4 (1.0%)
Foam	217 (96.4%)	176 (96.7%)	393 (96.6%)
Other non-trial	5 (2.2%)	4 (2.2%)	9 (2.2%)

treated' analysis,[69] where (after excluding those patients who did not satisfy the trial eligibility criteria), patients who received the correct randomised mattress at baseline and then changed mattresses were treated as 'censored' at the first treatment change (any pressure ulcers occurring after the mattress change were excluded). The results of this analysis were very similar to the ITT analysis, which suggests that the mattress changes do not impact upon the main trial conclusion. However, the 'as-treated' result should be treated with caution as this analysis is subject to possible selection bias because it no longer respects the randomisation, and patients who change mattresses may be at a higher (or lower) risk of developing a pressure ulcer compared with

TABLE 33 *Existing grade 2 pressure ulcers at the baseline assessment (ITT population)*

	Overlay (*n* = 989)	Replacement (*n* = 982)	Total (*n* = 1971)
Patients with existing pressure ulcer	59 (6.0%)	54 (5.5%)	113 (5.7%)
Number of existing pressure ulcers per patient			
1	39 (66.1%)	35 (64.8%)	74 (65.5%)
2	14 (23.7%)	14 (25.9%)	28 (24.8%)
3	5 (8.5%)	2 (3.7%)	7 (6.2%)
4	1 (1.7%)	3 (5.6%)	4 (3.5%)
Total number of existing ulcers (% of total)	86 (51.5%)	81 (48.5%)	167
Location of existing pressure ulcers *n* (% of total number of existing ulcers)			
Sacrum	21 (24.4%)	25 (30.9%)	46 (27.5%)
Buttocks	41 (47.7%)	36 (44.5%)	77 (46.2%)
Heels	12 (13.9%)	9 (11.1%)	21 (12.6%)
Hips	2 (2.3%)	2 (2.4%)	4 (2.4%)
Other[a]	10 (11.6%)	9 (11.1%)	19 (11.4%)
[a]Location of other sites			
Elbow	3 (3.5%)	5 (6.2%)	8 (4.8%)
Ankle	4 (4.7%)	2 (2.5%)	6 (3.6%)
Foot	1 (1.2%)	0 (0%)	1 (0.6%)
Lower leg	1 (1.2%)	2 (2.5%)	3 (1.8%)
Miscellaneous	1 (1.2%)	0 (0%)	1 (0.6%)

patients who remain on the randomised mattress throughout the trial.

For those patients who developed a new pressure ulcer, 25.5% (27/106) of patients in the overlay group and 20.8% (21/101) of patients in the replacement group had changed mattresses before their new pressure ulcer developed. Statistical methods to investigate the effect of mattress compliance on the analysis of the primary end-point were investigated, but no suitable methods were found to account for patients changing to a non-trial treatment, rather than swapping to the opposing trial mattress. Further analysis will be undertaken using survival analysis to investigate the effect of the timing of mattress changes on the analysis of time to development of a new pressure ulcer.

Secondary end-points

Healing of existing pressure ulcers

A total of 113 (5.7%) patients had one or more existing grade 2 pressure ulcers at the baseline skin assessment, corresponding to 59 (6.0%) patients in the overlay group and 54 (5.5%) patients in the replacement group. *Table 33* summarises the number and locations of existing pressure ulcers for each patient. Most existing pressure ulcers were on the sacrum (n = 46, 27.5%) or buttocks (n = 77, 46.2%). Analyses and summaries were conducted on an ITT basis only, for those patients with an existing pressure ulcer.

Overall, 39 (34.5%) patients' ulcers healed, on 20 (33.9%) patients in the overlay group and 19 (35.2%) patients in the replacement group (*Table 34*). A log-rank test was used to compare time to healing between the mattress groups; the results are presented in *Table 35* and *Figure 6* shows the Kaplan–Meier curve. There was no evidence of a difference between the mattress groups with respect to time to healing (p = 0.86). The Kaplan–Meier estimate of the median time to healing was 20 days for each mattress group.

Final ulcer grade and surface area of existing ulcers

Table 36 summarises the total existing ulcer area per patient at the baseline and final skin assessments.

The final ulcer area was the total area of any existing ulcers at the last assessment where an ulcer tracing was taken. If the existing pressure ulcers for a patient had all healed during the trial, then the patient was assigned a final ulcer area of 0 cm^2. Existing pressure ulcers in the overlay group were slightly smaller at baseline, with a

TABLE 34 *Healing of existing grade 2 pressure ulcers (ITT population)*

	Overlay	Replacement	Total
Number of patients healed[a]	20/59 (33.9%)	19/54 (35.2%)	39/113 (34.5%)

[a] Complete healing, i.e. all existing pressure ulcers healed.

TABLE 35 *Analysis of time to healing (days)*

	Overlay Kaplan–Meier estimate of median time (95% CI)	Replacement Kaplan–Meier estimate of median time (95% CI)	χ^2	*p*
ITT population (n = 113)	20 (12 to NE)	20 (10 to NE)	0.03	0.86

NE, upper confidence limit not estimable.

median area of 0.7 cm^2 (range 0.1–29.2 cm^2) compared with a median area of 1.2 cm^2 (range 0.1–48.9 cm^2) for patients in the replacement group. There was little difference between the mattress groups in the final ulcer area; the median final ulcer area for the overlay group was 0 cm^2 (range 0–20.1 cm^2) and 0.1 cm^2 (range 0–18.4 cm^2) for the replacement group. Forty-four (39%) patients with an existing ulcer at baseline did not have any ulcer tracings taken postbaseline, so no statistical analysis of the reduction in ulcer area has been undertaken. Reasons for missing tracings were investigated and were mostly because the patient had no further follow-up skin assessments (owing to death, discharge or ward transfer) for nine overlay and six replacement patients, a dressing was in place for five overlay and four replacement patients, or because the CRN commented that they were unable to trace the ulcer owing to patient pain or no clear wound edges (three overlay and one replacement patient). No reasons were giving for the missing tracings for the remaining 16 patients.

Tables 37 and *38* summarise the final ulcer grade at trial completion of existing ulcers, on an ulcer and a per-patient basis, respectively. The maximum final ulcer grade per patient (the most severe grade at the final skin assessment of all existing pressure ulcers) was compared between the mattress groups using a Cochran–Armitage test for trend and there was no evidence of a difference (z = –0.045, p = 0.96). There was a higher incidence of dressings being in place over existing ulcers, at the final skin assessment, for patients in the overlay group. Excluding these patients from the analysis may be a source of potential bias as the presence of a dressing could indicate that these ulcers were larger and of a more severe grade.

For the patients that healed during the trial, one patient in the overlay group and one patient in the replacement group had a missing final skin assessment as the CRN was unable to view the site; one patient in the replacement group had a dressing in place and one patient in the replacement group had a grade 1a that increased to a grade 2 at trial completion. The remaining 19 patients in the overlay group and 16 patients in the replacement group remained healed at trial completion.

Patient acceptability

There were two end-points measuring the acceptability of the mattresses. These were the numbers of patients who requested a mattress change because of dissatisfaction with the alternating pressure device and the recording on the patient acceptability form of whether or not the patient experienced any problems with any aspect of the mattress.

Table 39 details the patient-requested mattress changes, including 240 (24.3%) patients in the overlay group and 192 (19.6%) patients in the replacement group who requested at least one mattress change during the trial period. Most patients only requested one mattress change during the trial, with four patients requesting two changes. Most of the mattress changes were because of comfort, corresponding to 413/436

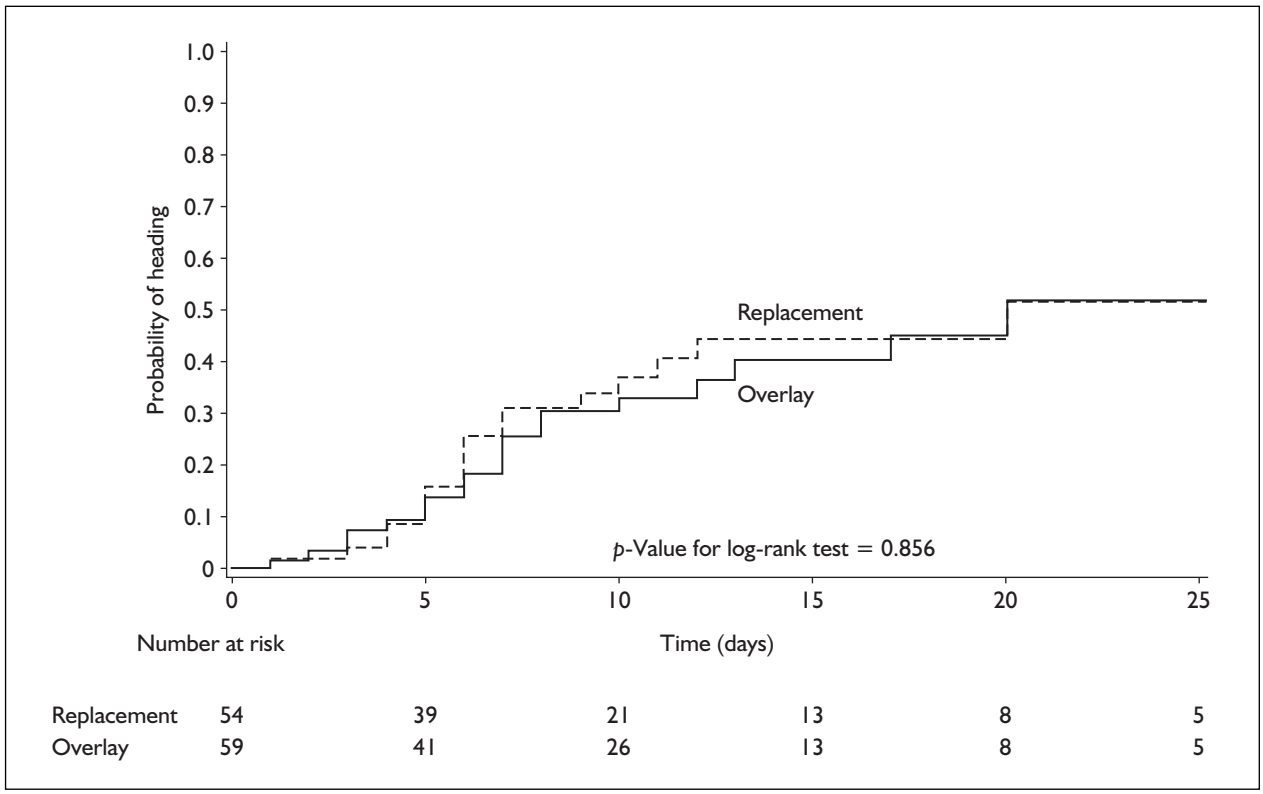

FIGURE 6 *Kaplan–Meier plot of time to complete healing of existing pressure ulcers (ITT population)*

TABLE 36 *Total surface area of existing pressure ulcers per patient (ITT population)*

	Overlay (*n* = 59)	**Replacement (*n* = 54)**	**Total (*n* = 113)**
Baseline ulcer area (cm^2)			
Mean (SD)	2.3 (4.4)	3.9 (7.9)	3.1 (6.4)
Median (range)	0.7 (0.1–29.2)	1.2 (0.1–48.9)	0.9 (0.1–48.9)
Missing	5	2	7
Final ulcer area (cm^2)			
Mean (SD)	1.6 (4.3)	2.1 (4.3)	1.8 (4.3)
Median (range)	0.0 (0.0–20.1)	0.1 (0.0–18.4)	0.1 (0.0–20.1)
Missing	26	18	44
Absolute change in area (cm^2) (baseline – final)[a]			
Mean (SD)	1.0 (2.3)	2.0 (6.1)	1.6 (4.7)
Median (range)	0.4 (–3.7 to 9.2)	0.3 (–6.0 to 30.5)	0.4 (–6.0 to 30.5)
Missing	26	18	44
Percentage change in area (baseline – final)[a]			
Mean (SD)	–35 (605.5)	34.4 (108.6)	1.3 (424.0)
Median (range)	100 (–3400 to 100.0)	91.8 (–405 to 100.0)	98.8 (–3400 to 100.0)
Missing	26	18	44

[a] For ulcers with a baseline and at least one postbaseline tracing, patients who healed were assigned a final total ulcer area of 0 cm^2.

TABLE 37 *Ulcer grade at trial completion of existing pressure ulcers (ITT population)*

	Overlay (*n* = 86)	Replacement (*n* = 81)	Total (*n* = 167)
Ulcer grade (% of number of existing ulcers)			
0	3 (3.5%)	4 (4.9%)	7 (4.2%)
1a	14 (16.3%)	9 (11.1%)	23 (13.8%)
1b	16 (18.6%)	13 (16.0%)	29 (17.4%)
2	34 (39.5%)	43 (53.1%)	77 (46.1%)
3	1 (1.2%)	4 (4.9%)	5 (3.0%)
5	2 (2.3%)	0 (0%)	2 (1.2%)
Dressing *in situ*/unable to view	16 (18.6%)	8 (9.9%)	24 (14.4%)

TABLE 38 *Maximum ulcer grade at trial completion per patient*

	Overlay (*n* = 59)	Replacement (*n* = 54)	Total (*n* = 113)
Maximum grade at trial completion per patient[a]			
0	1 (1.7%)	3 (5.6%)	4 (3.5%)
1a	8 (13.6%)	4 (7.4%)	12 (10.6%)
1b	10 (16.9%)	9 (16.7%)	19 (16.8%)
2	25 (42.4%)	28 (51.9%)	53 (46.9%)
3	1 (1.7%)	4 (7.4%)	5 (4.4%)
5	2 (3.4%)	0 (0%)	2 (1.8%)
Dressing *in situ*/unable to view	12 (20.3%)	6 (11.1%)	18 (15.9%)

[a] For patients with more than one existing pressure ulcer, the maximum grade of any pressure ulcer at the last recorded skin assessment.

TABLE 39 *Patient-requested mattress changes (ITT population)*

	Randomised mattress		
	Overlay (*n* = 989)	Replacement (*n* = 982)	Total (*n* = 1971)
Patients requesting a mattress change	240 (24.3%)	192 (19.6%)	432 (21.9%)
Patients requesting a change owing to comfort or other mattress-related reasons	230 (23.3%)	186 (18.9%)	416 (21.1%)
Number of times a change was requested			
1	237 (24.0%)	191 (19.5%)	428 (21.7%)
2	3 (0.3%)	1 (0.1%)	4 (0.2%)
Reason for change			
Comfort	231 (95.1%)	182 (94.3%)	413 (94.7%)
Mattress no longer required[a]	11 (4.5%)	7 (3.6%)	18 (4.1%)
Other mattress-related reason	0 (0%)	4 (2.1%)	4 (0.9%)
Reason not given	1 (0.4%)	0 (0%)	1 (0.3%)
Total number of changes	243	193	436
Mattress changed to (% of total number of changes)			
Overlay	0 (0%)	1 (0.5%)	1 (0.2%)
Replacement	3 (1.2%)	2 (1.0%)[b]	5 (1.1%)
Foam	233 (95.9%)	186 (96.4%)	419 (96.1%)
Other non-trial	7 (2.9%)	4 (2.1%)	11 (2.5%)
Time to first mattress change (days)			
Mean (SD)	3.4 (3.3)	4 (3.5)	3.7 (3.4)
Median (range)	3 (0–34)	3 (0–25)	3 (0–34)

[a] Owing to improved mobility/activity or pressure ulcer healed.
[b] Patient changed to a different type of replacement mattress.

changes (94.7%), and most mattresses were changed to a high-specification foam mattress.

A χ^2 test was used to compare the two mattress groups (*Table 40*) for the difference in the proportions that requested a mattress change for comfort and other reasons. For the overlay group, 23.3% of patients requested a change compared with 18.9% of patients in the replacement group, a difference of 4.4% (95% CI 0.7 to 7.9%), which was statistically significant ($\chi^2 = 5.51$, $p = 0.02$).

Table 41 provides details of the patient acceptability questions, by the actual mattress on which the patient was placed at the baseline assessment, rather than the randomised mattress. At trial completion patients were asked on a yes/no basis whether the mattress was noisy or interfered with sleep, whether the motion of the mattress affected them, whether the mattress affected their movement in bed and getting into/out of bed, mattress temperature and whether the overall comfort was acceptable. They were also given the opportunity to provide further comments relating to mattress motion, movement, temperature and general issues.

Of the 1820 patients who received a trial overlay or replacement mattress at baseline, 1583 (86.9%) provided mattress acceptability information. Patients without any acceptability data had been discharged from hospital or were too ill or confused to answer the questions at the time of trial completion. Of the seven acceptability questions, more patients in the overlay group than in the replacement group reported the mattress to be unacceptable in six of the categories (*Table 41* and *Figure 7*), including overall comfort, which was reported as unacceptable by 29.5% of patients in the overlay group compared with 24.4% of patients in the replacement group. A total of 1010 (63.8%) patients had one or more negative responses, with more than one-third of patients reporting difficulties associated with movement in bed and getting into/out of bed for both overlay and replacement mattresses.

A large number of patients also provided further comments about the mattresses, including positive, negative and equivocal descriptions of the mattress characteristics in relation to motion, movement, temperature and general issues about the mattresses.

TABLE 40 *Analysis of patients requesting a mattress change owing to dissatisfaction with the pressure-relieving mattress*

	Overlay (%)	Replacement (%)	Difference (95% CI)	χ^2	*p*
ITT population ($n = 1971$)	23.3	18.9	4.4 (0.7 to 7.9)	5.51	0.02

TABLE 41 *Patient acceptability question responses*

	Actual mattress received at baseline		
	Overlay ($n = 929$)	Replacement ($n = 891$)	Total[a] ($n = 1820$)
Patients with acceptability data	817 (87.9%)	766 (86.0%)	1583 (86.9%)
Patients who experienced a problem with each acceptability item (% of patients with acceptability data)			
Mattress noise	107 (13.1%)	115 (15%)	222 (14.0%)
Interference with sleep	150 (18.4%)	139 (18.1%)	289 (18.3%)
Affected by mattress motion	103 (12.6%)	85 (11.1%)	188 (11.9%)
Movement in bed	307 (37.6%)	271 (35.4%)	578 (36.5%)
Movement getting into/out of bed	302 (37%)	263 (34.3%)	565 (35.7%)
Temperature	94 (11.5%)	79 (10.3%)	173 (10.9 %)
Overall comfort	241 (29.5%)	187 (24.4%)	428 (27.0%)
Number of patients with one or more negative responses	525 (64.3%)	485 (63.3%)	1010 (63.8%)

[a] 151 patients were allocated a non-trial mattress at baseline and have not been included in these summaries.

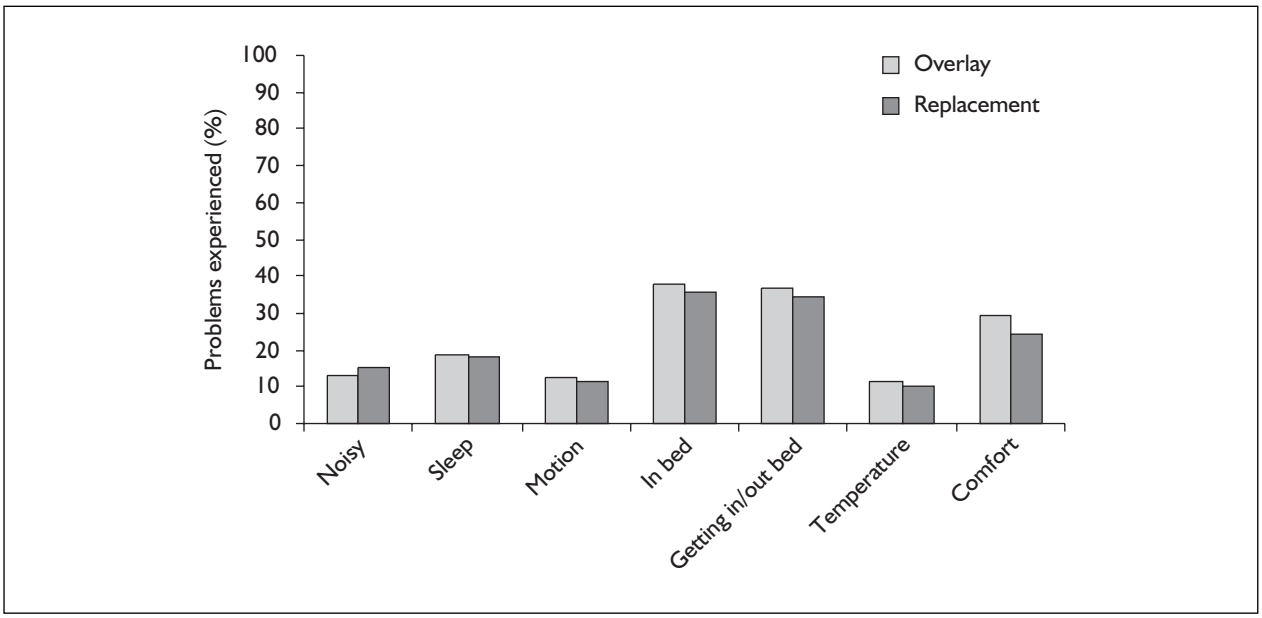

FIGURE 7 *Patients experiencing a problem with each aspect of mattress acceptability, by actual mattress received at baseline*

TABLE 42 *Patient acceptability open responses: mattress motion*

	Actual mattress received at baseline		
	Overlay (*n* = 929)	**Replacement (*n* = 891)**	**Total[a] (*n* = 1820)**
Number of patients commenting on mattress motion (% of patients with acceptability data)	610 (74.7%)	555 (72.5%)	1165 (73.6%)
Negative	328 (40.1%)	285 (37.2%)	613 (38.7%)
Positive	272 (33.3%)	263 (34.3%)	535 (33.8%)
Equivocal	95 (11.6%)	86 (11.2%)	181 (11.4%)

Some patients may have made more than one comment about mattress motion.

A total of 1165 (73.6%) patients provided comments relating to mattress motion, with similar numbers of positive and negative comments including the effects on sleep, nausea, pain and comfort resulting from hard (or soft) ridges and the alternating cycle/vibration (*Table 42*). There were more positive comments and fewer negative comments by patients provided with a replacement mattress than by those provided with an overlay mattress. Comments included general negative comments such as "very uncomfortable due to ridges", "felt to be in a dip", "caused a ridge across my back like a wooden bar" and "didn't like it – it hissed when I moved"; general positive comments such as "I was very, very comfortable", "it was quite comforting", "liked the motion – felt it gave a gentle massage when you moved" and "overall comfortable – slept like a log"; and equivocal comments, such as "was aware of motion but got used to it" and "felt cells deflating but not too unpleasant".

Seven-hundred and forty-eight (47.3%) patients made comments relating to movement in bed and getting into/out of bed, and these were in the main negative for both the overlay and replacement mattresses (*Table 43*), with patients reporting difficulties associated with the soft edges, gaps between cells and ridges. For example, comments relating to movement in bed included, "surface too soft to move easily", "difficult to move up the bed due to ridges", "sank whenever I moved", "sank down when pushing up", "hands and feet slipped in gaps" and "impossible to get up the bed", although positive comments were also made, for example, "found the ridges useful to move up the bed". Some patients reported a feeling of insecurity, "felt as though falling off the

TABLE 43 *Patient acceptability open responses: movement in bed/getting into/out of bed*

	Actual mattress received at baseline		
	Overlay (*n* = 929)	**Replacement (*n* = 891)**	**Total[a] (*n* = 1820)**
Number of patients commenting on movement (% of patients with acceptability data)	391 (47.9%)	357 (46.6%)	748 (47.3%)
Negative getting into/out of bed	124 (15.2%)	127 (16.6%)	251 (15.9%)
Negative movement in bed	290 (35.5%)	260 (33.9%)	550 (34.7%)
Positive	25 (3.1%)	27 (3.5%)	52 (3.3%)
Equivocal	15 (1.8%)	10 (1.3%)	25 (1.6%)

Some patients may have made more than one comment about movement.

TABLE 44 *Patient acceptability open responses: temperature*

	Actual mattress received at baseline		
	Overlay (*n* = 929)	**Replacement (*n* = 891)**	**Total[a] (*n* = 1820)**
Number of patients commenting on temperature (% of patients with acceptability data)	110 (13.5%)	88 (11.5%)	198 (12.5%)
Hot/warm	67 (8.2%)	50 (6.5%)	117 (7.4%)
Sweaty/sticky	32 (3.9%)	23 (3.0%)	55 (3.5%)
Cold/cool	11 (1.3%)	11 (1.4%)	22 (1.4%)
Other	17 (2.1%)	18 (2.3%)	35 (2.2%)

Some patients may have made more than one comment about temperature.

edge of the bed", "felt unstable when trying to use both arms to move about" and "ridges made bed feel unstable". Similarly, comments relating to getting in/out of bed included, "bed feels unsupportive when getting out", "very difficult to push upright to stand", "hands sank into ridges when pushing up to stand", "found it difficult to get legs in and out due to ridges", "it dipped at the ends making it hard to get out" and "no balance and safety when sitting on edge of bed". In addition, patients commented on the height of the bed in relation to getting into/out of bed and safety/security while in bed. Comments included, "bed too high", "mattress too high", "a bit high to get my legs back into bed" and "panicked about the height of the bed".

Additional comments were made by 198 (12.5%) of patients in relation to the temperature of the mattress (*Table 44*). The majority of patient comments indicated that the mattresses were too hot or warm or made them feel sticky and sweaty, for example, "tended to be too warm", "felt warm and sweaty" and "mattress tended to make me sweat". However, some patients indicated that it was other factors that were causing them to feel hot or warm, for example, 'hot and sweaty but weather same', and a small number of patients reported feeling cold.

Finally, 230 (14.5%) patients made general comments about other aspects of the mattresses, including the mattresses not working properly, difficulty with bed sheets and difficulty in using the backrest (*Table 45*). For example, "Sank in the middle, the mattress collapsed, all the air came out", "because you can't tuck sheets in properly they crease under me", "bedclothes tended to slip off mattress" and "the mattress was too high and so I couldn't pull the back rest". In addition, there were general comments which overlapped with the emerging themes identified in relation to movement in bed and getting into/out of bed, including bed/mattress height, mattress slippy, mattress soft, edges soft and edges slope.

Safety

Adverse events

In total, 377 adverse events were reported for 308 patients. Nine mattress-related adverse events

TABLE 45 *Patient acceptability open responses: general comments*

	Actual mattress received at baseline		
	Overlay (*n* = 929)	**Replacement (*n* = 891)**	**Total[a] (*n* = 1820)**
Number of patients with a general comment (% of patients with acceptability data)	130 (15.9%)	100 (13.1%)	230 (14.5%)
Mattress not working/not working properly	16 (2.0%)	18 (2.3%)	34 (2.1%)
Hard to tuck sheet under/sheets come off or gather/mattress cover slips	19 (2.3%)	6 (0.8%)	25 (1.6%)
Mattress/bed too high	72 (8.8%)	48 (6.3%)	120 (7.6%)
Mattress slippy	9 (1.1%)	4 (0.5%)	13 (0.8%)
Mattress too soft/edges soft or slope	19 (2.3%)	29 (3.8%)	48 (3.0%)
Not able to use backrest	4 (0.5%)	2 (0.3%)	6 (0.4%)
Other[a]	2 (0.2%)	0	2 (0.2%)

[a] Other comments, such as mattress smells, dye comes out of mattress.
Some patients may have made more than one comment.

TABLE 46 *Adverse events*

	Mattress at time of event				
	Overlay	**Replacement**	**Foam**	**Other non-trial**	**Total**
Mattress related					
Fall	0	4	0	0	4
Other	2	3	0	0	5
Suspected contact dermatitis	0	1	0	0	1
Climbed over/fell through cot sides	2	1	0	0	3
Mattress deflation during transfer	0	1	0	0	1
Not mattress related but equivocal					
Fall	3	5	0	1	9
Other	0	2	1	0	3
Unstable fracture	0	1	1	0	2
Pain in left hip	0	1	0	0	1
Not mattress related					
Fall	13	6	10	1	30
Cardiac arrest	10	7	3	2	22
Hypothermia	2	0	0	0	2
Hyperthermia[a]	13	9	4	0	26
Other	106	112	39	19	276

[a] Classified as hyperthermia by CRN, but reported body temperature was <41°C.

were reported for eight patients, including two incidents (one patient) on an overlay mattress at the time of the event and seven incidents on replacement mattresses at the time of the event (*Table 46*). Adverse events reported as mattress related included four falls (all on mattress replacements), three cot-side incidents (two patients, one on overlay and one on replacement), one suspected contact dermatitis (replacement mattress) and one incident where the patient caught their back on the bed rail as the mattress deflated during transfer (replacement mattress).

The remaining 368 adverse events reported by the CRNs were categorised as 'not mattress related', and of these 12 were upgraded by the TMG/TSC to 'equivocal'. This included nine falls (three overlay, five replacement, one other non-trial mattress), two reports of increased pain due to screw movement in the fracture (one replacement

TABLE 47 *Deaths (ITT population)*

	Randomised mattress		
	Overlay	**Replacement**	**Total**
Total number of deaths	83/989 (8.4%)	69/982 (7.0%)	152/1971 (7.7%)
Died before end of trial period	55 (5.6%)	45 (4.6%)	100 (5.1%)
Died after trial completion but before discharge	28 (2.8%)	24 (2.4%)	52 (2.6%)
Acute admissions	76/488 (15.6%)	65/483 (13.5%)	141/971 (14.5%)
Died before end of trial period	52 (10.7%)	42 (8.7%)	94 (9.7%)
Died after trial completion but before discharge	24 (4.9%)	23 (4.8%)	47 (4.8%)
Elective admissions	7/501 (1.4%)	4/499 (0.8%)	11/1000 (1.1%)
Died before end of trial period	3 (0.6%)	3 (0.6%)	6 (0.6%)
Died after trial completion but before discharge	4 (0.8%)	1 (0.2%)	5 (0.5%)
Patients with an existing grade 2 pressure ulcer	20/59 (33.9%)	12/54 (22.2%)	32/113 (28.3%)
Died before end of trial period	14 (23.7%)	6 (11.1%)	20 (17.7%)
Died after trial completion but before discharge	6 (10.2%)	6 (11.1%)	12 (10.6%)

and one foam mattress) and one report of increased pain in the left hip (one replacement mattress). The latter was flagged by the TSC as requiring medical opinion, which was sought by the CRN team leader through discussion with a consultant orthopaedic surgeon.

Adverse events classed by the CRNs as hyperthermia did not fulfil the definition of a body temperature of 41°C or higher, and are therefore not of concern. Adverse events classified by the CRNs as 'other' included medical and postoperative complications and problems (such as haemodynamically unstable, vasovagal attack, low postoperative haemoglobin and haematemesis) and patient death. Further summaries of 'not mattress-related' events are presented in *Table 46*.

Deaths

Table 47 summarises the number of deaths, by randomised mattress, admission type and the presence of an existing grade 2 pressure ulcer at the baseline assessment. A total of 152 (7.7%) patients died, with 100 (5.1%) dying before the end of the 60-day trial period and 52 (2.6%) dying after trial completion but before hospital discharge. Slightly more patients in the overlay group died either during the trial or before discharge than in the replacement group [83 (8.4%) patients compared with 69 (7%) patients in the replacement group]. There were more deaths among patients who were acute admissions (n = 141, 14.5%) compared with elective admissions (n = 11, 1.1%). There were also more deaths among patients with an existing grade 2 pressure ulcer, with 32 (28.3%) patients dying, of whom 20 (17.7%) died during the trial period and 12 (10.6%) died after trial completion but before hospital discharge.

Mattress technical problems

Table 48 summarises mattress technical problems, by the actual mattress the patient was on at the time the problem was reported. Details of whether the mattress was working correctly were collected at the baseline assessment and at each subsequent follow-up assessment. More overlay mattresses had a technical problem, with a total of 207 problems reported for 131 overlay mattresses, compared with a total of 172 problems reported for 92 replacement mattresses. Further details of the problems reported are provided in *Table 48*. The most commonly reported problem was that the mattress had deflated or had low pressure (94 occurrences or 24.8% of all problems).

Summary

There was no evidence of a difference between the overlay and replacement mattresses with respect to the incidence of new grade 2 pressure ulcers. In the primary ITT analysis, 10.7% of patients in the overlay group and 10.3% of patients in the replacement group developed one or more new grade 2 pressure ulcers during the trial period. The difference in proportions (overlay – replacement) was small at 0.4% (95% CI –2.3% to 3.1%), which was not statistically significant (χ^2 = 0.1, p = 0.75). This was confirmed by the adjusted analysis (p = 0.7) and by analysis of the pp population (χ^2 = 0.29, p = 0.59).

TABLE 48 *Mattress technical problems*

	Overlay	Replacement	Total
Mattresses with a technical problem	131	92	223
Total number of problems reported	207	172	379
All technical problem details[a]			
Plug/electricity supply not turned on	40 (19.3%)	33 (19.2%)	73 (19.3%)
Transport/static mode	4 (1.9%)	25 (14.5%)	29 (7.7%)
Cardiopulmonary resuscitation	24 (11.6%)	4 (2.3%)	28 (7.4%)
Connectors/tubing/mattress position	8 (3.9%)	11 (6.4%)	19 (5.0%)
Settings	53 (25.6%)	12 (7.0%)	65 (17.2%)
Alarming	20 (9.7%)	31 (18.0%)	51 (13.5%)
Deflated/low pressure	49 (23.7%)	45 (26.2%)	94 (24.8%)
Pump failure	0 (0%)	3 (1.7%)	3 (0.8%)
Broken part	4 (1.9%)	6 (3.5%)	10 (2.6%)
Unknown	5 (2.4%)	2 (1.2%)	7 (1.8%)

[a] More than one technical problem may have been reported for a mattress.

There was also no evidence of a difference between the mattresses with respect to the time to development of the first new pressure ulcer (log-rank test statistic 0.094, $p = 0.76$). Most new ulcers ($n = 297$, 97.4%) reached a maximum grade of 2. The median value of the maximum total area of new pressure ulcers was 1.2 cm^2 (range 0.1–40.9 cm^2) for the overlay group and 1.1 cm^2 (range 0.1–68.1 cm^2) for the replacement group. The difference between the mattress groups was not statistically significant ($\chi^2 = 0.0005$, $p = 0.98$).

Ten per cent of patients in the overlay group and 9.3% of patients in the replacement group developed a new pressure ulcer within 30 days of randomisation; the difference between the mattress was not statistically significant ($\chi^2 = 0.31$, $p = 0.58$). The results for the development of a new ulcer within 30 days are similar to the primary end-point result and indicate that most of the new pressure ulcers developed within the first 30 days.

In the adjusted analysis, prognostic factors found to have a statistically significant effect on the likelihood of developing a new pressure ulcer were:

- admission type (acute patients had more than three times the risk of pressure ulcer development compared with elective patients)
- the presence of a wound, skin trauma or non-blanching erythema on any site at baseline (the presence of each of these led to an increased risk of pressure ulcer development)
- patient age (older patients were at an increased risk of pressure ulcer development)
- diabetes (patients who were diabetic had an increased risk of pressure ulcer development compared with non-diabetic patients)
- haemoglobin on admission (an increase in haemoglobin on admission was related to a decreased risk of pressure ulcer development).

There was no evidence of a difference between the overlay and replacement mattresses with respect to the time to healing of existing grade 2 pressure ulcers (log-rank test statistic 0.03, $p = 0.86$). One-hundred and thirteen (5.7%) patients had an existing pressure ulcer; of these, 33.9% of the patients in the overlay group and 35.2% of the patients in the replacement group healed completely during the trial. No statistical analysis of the reduction in ulcer area was performed owing to the high proportion of patients ($n = 44$, 39%) who did not heal but had no follow-up ulcer tracings.

For mattress acceptability, more patients in the overlay group (23.3%) requested a mattress change because they were dissatisfied with the mattress, compared with patients in the replacement group (18.9%). The difference between the mattress groups was statistically significant ($\chi^2 = 5.51$, $p = 0.02$) with a difference of 4.4% (95% CI 0.7 to 7.9%). More patients in the overlay group also withdrew from the trial because of comfort, with six of the 16 patients who withdrew giving comfort as their reason, compared to none of the five patients who withdrew in the replacement group.

In addition, more patients provided with an overlay mattress reported problems with aspects of mattress comfort, motion, movement in bed, getting into/out of bed, temperature and other general features than patients provided with a replacement mattress at baseline.

Chapter 4

Results of the health economic evaluation

Base-case analysis

Information from 1971 patients was included in the economic analysis: 989 individuals allocated to the alternating overlays and 982 to the alternating replacement mattresses. Details of the key unit costs, together with their sources, are presented in *Table 49*.

Descriptive statistics of mean length of stay in hospital as well as unadjusted mean costs in both groups are presented in *Table 50*. On average, individuals in the replacement mattress group spent 1 day less in hospital than those in the alternating overlay group. However, given the skewed nature of both cost and length of stay data, these unadjusted estimates of duration of hospitalisation and mean total costs are prone to bias. To adjust the estimates of mean differential length of stay in hospital and treatment costs between mattress groups, a GLM was used.

The GLM that best described length of stay and costs data included three independent variables: admission type (acute/elective), age and development of a new ulcer within 60 days. The coefficient estimates of a GLM with a link function represent the difference between groups in terms of arithmetic means. For example, the admissions coefficient indicated the difference in arithmetic means between acute and elective patients. The model indicated that a longer period of hospitalisation and greater costs were associated with acute admissions, older individuals and individuals who developed a pressure ulcer within 60 days (*Tables 51* and *52*). The coefficients associated with these variables were statistically significant.

Adjusted mean estimates of differential hospitalisation duration and total cost are described in *Tables 51* and *52*. The adjusted analysis indicated that on average individuals in

TABLE 49 *Description of unit costs*

Item	Unit cost	Source
Hospital costs		
Elderly	£165.00	CIPFA, 2003[42]
Orthopaedic	£385.00	CIPFA, 2003[42]
Vascular	£374.00	CIPFA, 2003[42]
Mattress (purchase)		
Overlay	£1010.50	Huntleigh Healthcare Ltd and Hill-Rom Retail Price List
Replacement	£4173.60	Huntleigh Healthcare Ltd and Hill-Rom Retail Price List
Mattress (daily rental cost)		
Overlay	£8.23	Huntleigh Healthcare Ltd and Hill-Rom Retail Price List
Replacement	£16.30	Huntleigh Healthcare Ltd and Hill-Rom Retail Price List

TABLE 50 *Unadjusted length of stay and costs*

	Unadjusted estimates	
Resource used	**Overlay**	**Replacement**
Length of stay in hospital (days)		
Mean (SD)	20.36 (25.72)	19.15 (21.54)
Median (range)	11 (0–224)	11 (0–204)
Total costs (unadjusted)		
Mean (SD)	£6793.33 (£8196.52)	£6509.73 (£7347.56)
Median (range)	£3863.80 (£0–74,184.96)	£3907.10 (£0–79,704.84)

TABLE 51 *GLM for duration of hospitalisation*

Variable	Coefficient (SE)	95% CI
Constant	–8.77 (2.40)	(–13.47 to 4.07)
Replacement mattress	–0.39 (0.60)	(–1.58 to 0.78)
Acute	11.71 (0.99)	(9.77 to 13.65)
Age	0.28 (0.04)	(0.22 to 0.35)
New pressure ulcer within 60 days	13.27 (2.51)	(8.35 to 18.19)

TABLE 52 *GLM for baseline hospital costs*

Variable	Coefficient (SE)	95% CI
Constant	–3251.50 (891.39)	(–4998.59 to –1504.40)
Replacement mattress	–74.50 (225.88)	(–517.21 to 368.21)
Acute	2721.24 (318.69)	(2096.64 to 3345.85)
Age	107.57 (13.01)	(82.08 to 133.07)
New pressure ulcer within 60 days	4566.44 (831.13)	(2937.47 to 6195.42)

TABLE 53 *Restricted Kaplan–Meier estimates of time to pressure ulcer onset*

Treatment group	Mean (days)	95% bias-corrected CI
Overlay	45.72	
Replacement	56.35	
Difference	–10.63	(–24.40 to 3.09)

TABLE 54 *Base-case analysis*

Overlay – replacement	Mean	95% bias-corrected CI
Differential health benefit	–10.63 days	(–24.40 to 3.09)
Differential cost	£74.50	(–£312.44 to £494.38)

the replacement mattress group spent less time in hospital, by 0.39 of a day (95% CI –1.58 to 0.78 days) (*Table 51*), than individuals in the overlay group. This translates to a reduction in costs of £74.50 in favour of the mattress replacement group (95% CI –£368.21 to £517.21, not statistically significant) (*Table 52*). Interactions between type of mattress and type of admission (elective or acute) were investigated in the GLMs for length of stay and total cost; however, no statistically significant interactions were identified. This means that the treatment effect (on total cost and length of stay) is not significantly affected by type of admission (acute or elective).

The health benefit associated with either surface was measured as the difference in mean time to a new pressure ulcer development between the alternating overlay and the replacement mattress groups within the trial period (i.e. the first 60 days). The difference in restricted Kaplan–Meier estimates of the mean time to new pressure ulcer development was in favour of the replacement mattress group. On average, individuals allocated to the alternating pressure mattress replacement developed a pressure ulcer 10.63 days later than those allocated alternating overlays (*Table 53*). However, this difference was not statistically significant (95% bias-corrected CI of the difference –24.40 to 3.09 days).

The base-case analysis described in *Table 54* shows that alternating replacement mattresses when compared with alternating overlays are a dominant strategy; that is, they are associated with a delay in the development of pressure ulcers and with lower hospital costs. In the presence of dominance an incremental analysis is not justified; therefore, the estimates of differential costs and health benefits were not combined in an ICER.

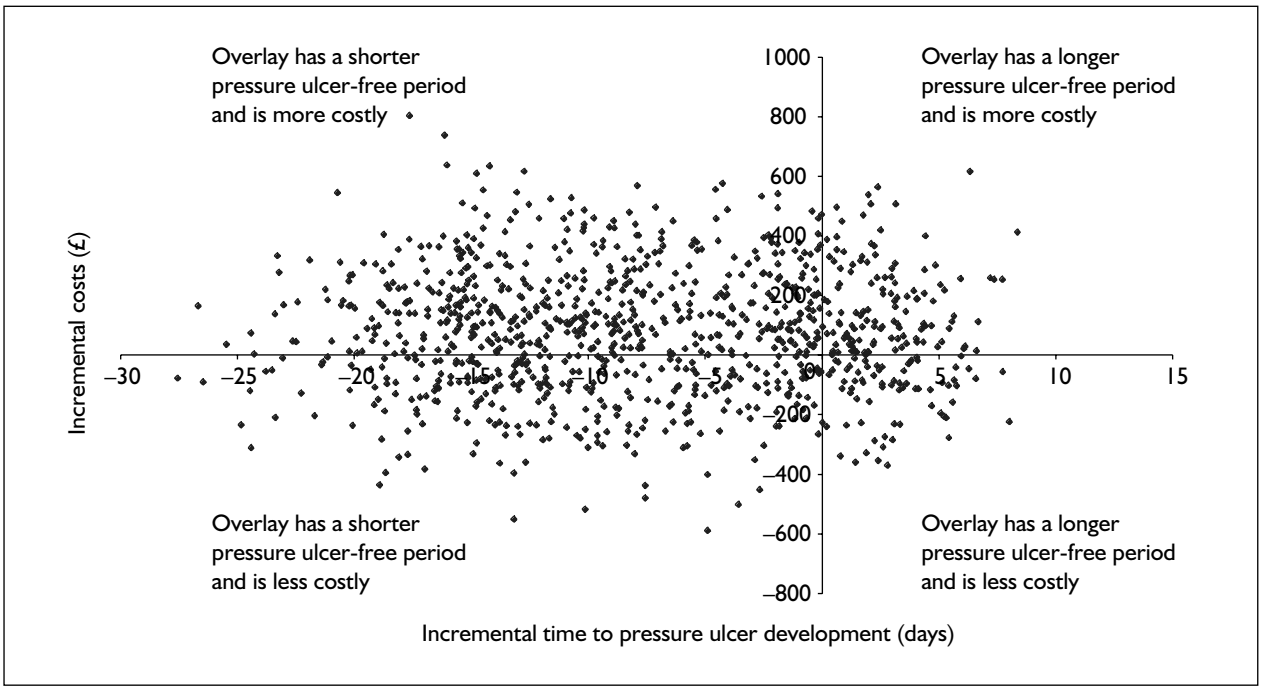

FIGURE 8 *Cost-effectiveness plane (base case)*

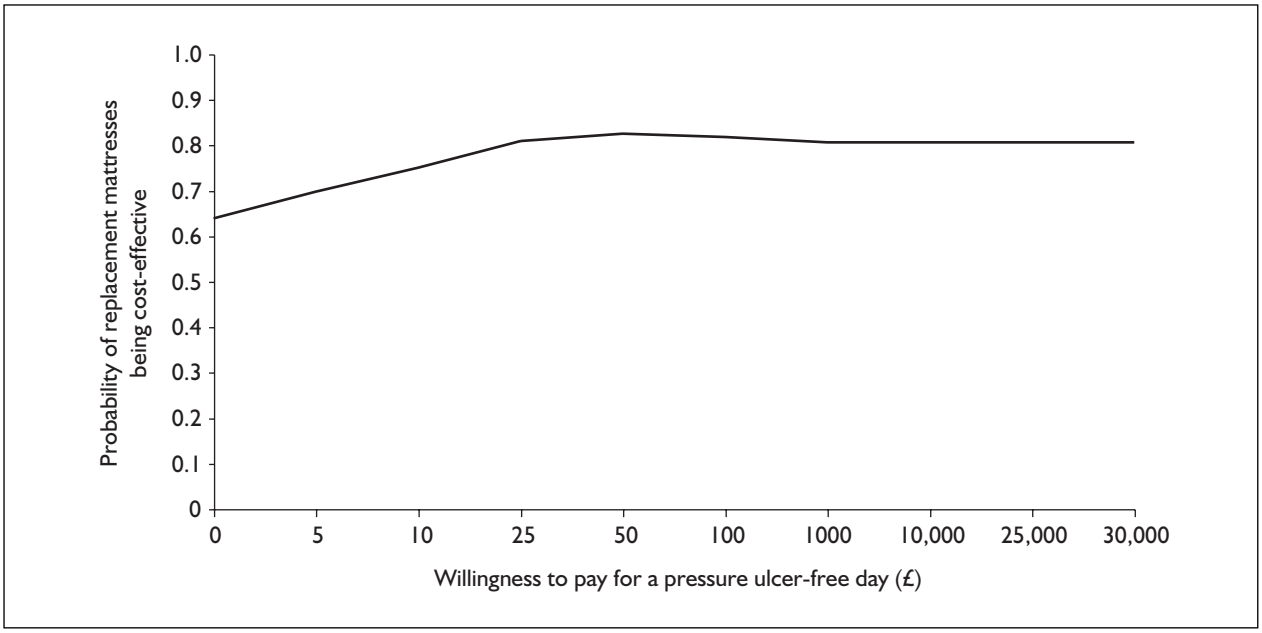

FIGURE 9 *CEAC for replacement mattress*

Sampling uncertainty of the mean difference in total costs and health benefits between overlay and replacement mattresses is represented in the incremental cost-effectiveness plane (*Figure 8*). The graph depicts the results of 1000 replicates of a non-parametric bootstrap of the mean difference in cost and benefits. As *Figure 8* shows, the largest proportion of point estimates falls in the second and third quadrants of the cost-effectiveness plane. This suggests that, in comparison with replacement mattresses, pressure-relieving overlays are associated with a shorter time to the onset of a pressure ulcer and greater costs.

The uncertainty associated with the decision to consider pressure-relieving overlays a dominated alternative when compared with replacement

TABLE 55 *Sensitivity analysis*

Overlay – replacement	Mean	95% bias-corrected CI
Differential cost (rental)	£29.81	(–£366.95 to £459.39)
Differential cost (5-year lifespan)	£108.36	(–£275.70 to £525.63)
Differential cost (7-year lifespan)	£114.42	(–£269.13 to £531.23)

mattresses is represented in *Figure 9*. In a situation of dominance, the level of uncertainty associated with the decision is represented as the probability of the intervention being cost-saving, that is, the probability associated with a willingness to pay of zero. This analysis indicates that the probability of alternating pressure mattress replacements being cost-saving when compared with alternating pressure overlays is 64%. A probability of less than 20% of being cost-effective was associated with overlay mattresses for a range of willingness-to-pay values (£0–30,000) for an extra pressure ulcer-free day.

Sensitivity analysis

Point estimates of the difference in costs between pressure-relieving surfaces under the three sensitivity analysis scenarios are shown in *Table 55*. Assuming that the pressure-relieving surfaces were rented rather than purchased by hospitals, the mean difference in the total treatment costs between overlay and replacement mattresses was reduced to £29.81. In the two scenarios that considered a longer lifespan for both pressure-relieving surfaces, the difference in total treatment cost was larger than that estimated in the base-case scenario: £74.50. The mean differential cost in the second and third sensitivity analyses was £108.36 and £114.42, respectively. In none of the three scenarios considered for sensitivity analysis was the difference in costs statistically significant at the 5% level (*Table 55*).

Cost-effectiveness planes for the base-case analysis and the three sensitivity analysis scenarios are presented in *Figure 10*. As the figure shows, the results from the base-case analysis were fairly robust to considering feasible variations in the lifespan of both pressure-relieving surfaces and changes in the provision of pressure-relieving surfaces to the hospital (renting rather than purchasing alternating overlays and replacement mattresses). The three sensitivity analyses suggested that, in comparison with replacement mattresses, alternating overlays are more costly and are associated with a shorter time to the development of new grade 2 pressure ulcers.

Summary

The cost-effectiveness analysis, based on the clinical and economic data from 1971 participants in the PRESSURE study, indicated that alternating pressure-relieving overlays are a dominated alternative. In other words, compared with alternating pressure replacement mattresses, alternating pressure overlays are associated with a shorter time to the development of a pressure ulcer and greater cost. On average, individuals on alternating pressure mattress replacements took 10.63 days longer to develop a pressure ulcer and their overall hospitalisation costs were £74.50 less than those of individuals in the overlay group. These results were robust to variations in the purchasing cost and lifespan of both alternating pressure-relieving surfaces.

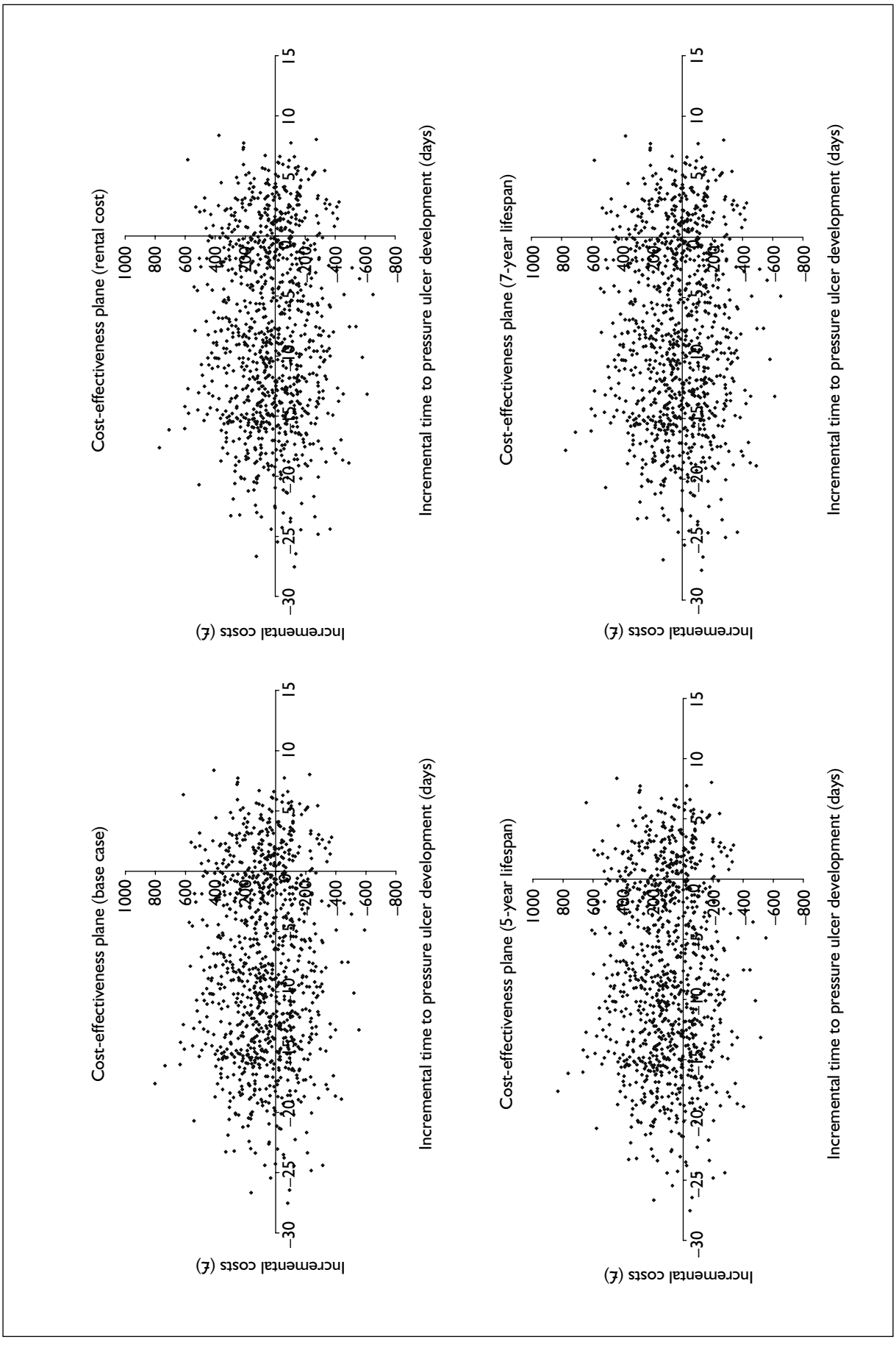

FIGURE 10 *Sensitivity analysis cost-effectiveness planes*

Chapter 5

Results of the quality of life substudy

Baseline data

The interviews were carried out during April 2002 to April 2004. Twenty-three people with personal experience of pressure ulceration (five men and 18 women) were recruited from four sites in the north of England. Interviews were not restricted to those who would have fulfilled eligibility criteria for the trial, with the aim of gaining insights into the impact of pressure ulceration on a wide range of people including those younger than the trial participants. Twenty-one participants were interviewed by EAN. KS interviewed two men towards the end of the study purposively to increase the numbers of male participants. *Tables 56* and *57* present characteristics of the participants and reasons for their admission. Twenty-one participants were approached for follow-up interview. (Follow-up interviews were not carried out with the two men interviewed later, owing to time restrictions.) Of those approached, seven agreed (three men and four women). Reasons for non-follow-up of 14 patients included decline in condition (n = 1), change of address (n = 1) and death (n = 3), and nine did not reply to the letters.

TABLE 56 *Characteristics of the participants*

	Male (n = 5)	Female (n = 18)
Age (years)		
Range	33–86	40–92
Median	78	78
Centre[a]		
1	3	10
2	0	1
3	0	4
4	2	3
Location of ulcer		
Heel	1	6
Sacrum	2	9
Buttock	0	1
Heel and buttock	0	1
Heel and sacrum	1	1
Sacrum and buttock	1	0
Grade of ulcer		
1	0	0
2	3	3
3	1	6
4	1	3
5	0	2
Not stated	0	4
Mobility before admission		
Fully mobile	1	8
Wheelchair	3	5
Walking sticks	0	2
Frame/wheelchair	2	3

[a] To ensure patient anonymity numbering of the centres for the quality of life substudy does not relate to the numbering of the main study centres.

Findings

The interviews with patients explored how they perceive and describe their health and quality of life, their experiences of developing a pressure ulcer and their experiences of pressure area care. Findings are presented to reflect the study's objectives. First, patient descriptions of their health and quality of life provide contextual detail and insights into the conditions of patients before they developed a pressure ulcer. However, descriptions of health and quality of life are also presented within findings describing patients' experiences of developing a pressure ulcer and their experiences of pressure area care. These later sections reveal the impact of the development of an ulcer and its treatment on the patients' perceptions of their health and quality of life.

Patients' descriptions of their health and quality of life

Interviews were carried out with a mainly elderly population. Although the age range was 33–92 years, 16 (69.5%) of the patients were aged over 70 years, the median age for both male and female participants being 78 years. The presence of co-morbidities is described as it was felt that participants' experiences of developing a pressure ulcer may be related to their health state at the time of development. It is important to note that 21 of the participants (91.3%) reported that they had some sort of chronic condition. This was relevant to discussions about their perceptions of their health and their quality of life, with the chronic condition influencing these perceptions.

Chronic conditions mentioned by participants included multiple sclerosis, Parkinson's disease,

TABLE 57 *Reason for hospital admission*

Patient number	Gender	Patient age (years)	Reason for admission	Other conditions
1	Male	56	Pressure ulcers	Degenerative spinal condition
2	Female	90	Fall and fractured hip	Arthritis
3	Female	48	Fall	Multiple sclerosis/ovarian cyst
4	Male	78	Road traffic accident	Prostate cancer
5	Female	76	Amputation (leg)	Osteoporosis
6	Female	68	Infected amputation stump	Amputation (leg)/diabetes
7	Female	68	Broken leg	Stroke
8	Female	75	Angioplasty (three cardiac arrests during procedure)	
9	Female	79	Fall and fractured hip	Diabetes/arthritis
10	Female	85	Pressure ulcer	Venous leg ulcers/myeloma
11	Female	40	Pressure ulcer	Multiple sclerosis
12	Female	78	Ischaemic leg	Diabetes
13	Female	92	Fall and fractured pelvis	Angina/hiatus hernia/arthritis
14	Female	82	Fall	Previous stroke
15	Female	88	Hip replacement	
16	Female	63	Hip replacement following fall	Diabetes Amputation (above knee)
17	Male	33	Pressure ulcer	Spina bifida
18	Female	73	Fall and fractured hip	Parkinson's disease
19	Female	77	Fall and fractured hip	Osteoporosis/pneumonia
20	Female	79	Leg ulcers	Arthritis
21	Female	88	Road traffic accident	Bladder cancer
22	Male	78	Chronic lung infection	Osteoporosis
23	Male	86	Fall and fractured hip	Parkinson's disease Cancer of bowel Leg ulcers

stroke, other neurological conditions, arthritis, osteoporosis, leg ulcers, diabetes and cancer. These chronic conditions had numerous effects on the participants' perceived health and quality of life. The majority of participants (n = 20, 86.9%) raised the issue of their 'dependence on others' during interview. The level of dependence varied greatly, with some participants requiring a care package from social services for assistance with ADL (such as washing and dressing). This care package often involved home carers, day centres and meals on wheels. Other participants reported requiring less help, usually provided by a family member or friend, for activities such as shopping. Twenty participants (86.9%) lived alone, two with their spouse and one with her teenage children.

There was wide variation in how participants felt about requiring assistance from a family member. Age appeared to be an important influence when participants discussed the care provided by home carers and family members. The following examples highlight the discrepancy, with carers being described as "marvellous" by an older patient, while the younger patient views them as

decreasing her ability to make choices. The first quotation is from a 79-year-old patient; the second patient is 48 years old:

> "I have very good carers who come morning, noon and night. They're marvellous" (patient 9: 91).

> "But there are days, you know, you don't feel like doing it, but you don't have no choice those days. Because they [home carers] turn up. You've got no choice" (patient 3: 127).

This difference in opinion was also marked in the ways in which patients discussed the help that they received from family members. Younger participants were more likely to express that they felt they created an extra burden for family members:

> "But when I'm at home, as well I'm having to rely on other people to do things for me. If I can't get out, or I'm waiting for a District Nurse, I have to rely on other people to do my shopping or pay bills or post letters, whatever. Well it's not right nice for them. Because I mean, I'm having to rely on my sister to do that and she's got a job to go to. She's got a son to look after. She's got her own life to lead. So it's not nice" (patient 17: 184).

Living with a chronic condition, particularly where mobility was affected, had required some patients to adapt their living arrangements; for example, adapting stairways with chairlifts, widening doors for a wheelchair or installing a shower. For others it had required them to move to more suitable accommodation:

> "I thought one of these days I'm going to fall backwards. You can't always guarantee that you're going to go forwards! So I thought well that's it, I'll stay downstairs and put the house in for an exchange" (patient 3: 75).

Since many of the participants were living with a chronic condition, they reported the impact of this on their health and quality of life. This is an important context for understanding the subsequent impact of developing a pressure ulcer.

Patients' experiences of developing a pressure ulcer

Perceived cause of ulcer

All participants were asked whether they were aware of what had caused or contributed to the development of their pressure ulcer. Some patients had experienced pressure ulcers before, whereas for some this was their first experience of an ulcer. However, there were no apparent patterns in the data of pressure ulcer development related to whether this was a first ulcer or not. For example, lack of knowledge about ulcer applied to both of these categories of patient.

Over half of the participants (n = 12) attributed the development of their pressure ulcer to decreased mobility. They recognised the link between being bedbound or chairbound and creating pressure on areas of their skin:

> "Well my own understanding of a pressure sore is that it's something that occurs in some people when they're confined to a bed with all the accompanying non-movement and so forth" (patient 4: 55).

> "I've been sitting now since almost the beginning of December last year. I've got a reclining chair, much bigger than this, and I could feel the pressure coming on" (patient 22: 51).

The pressure caused by being confined to a bed or chair was also referred to as "scuffing" or "rubbing" and some patients indicated a belief that pressure damage was more likely to occur because of the condition of their skin being "tender" or "like paper".

When confined to a bed or chair, the patients also discussed difficulties associated with not being able to move independently. Often these patients were relying on nursing staff to help them to reposition. Patients commented that this was often not carried out as frequently as they would like and so some patients attempted to move themselves by pushing on their heels while in bed. However, these movements were also seen by patients as contributing to pressure ulcer development, and indeed there is evidence that shear or friction contributes to skin breakdown.[70]

> "Pushing on my heels to push myself up you see, that started the heels. And then being immobile too, as well. Gradually the pressure sores started on the buttocks as well you see" (patient 13: 55).

The pressure ulcers being experienced by patients with chronic conditions developed in hospital, at home or in a nursing home. For patients admitted with an acute event, for example road traffic accident or fall, the ulcers developed while in hospital, although one patient suggested that the ulcer developed as a result of the position of her foot during the accident. First signs of the pressure ulcer were sometimes noticed by the patient, but sometimes they were unaware that an ulcer was developing until a carer (nurse, physiotherapist, doctor, care assistant, home carer or relative)

informed them. Reasons provided for not noticing the ulcer include a lack of sensation, preoccupation with other conditions (e.g. patients who had a road traffic accident said they were more concerned about broken bones than an ulcer on their heel) and the ulcer developing in areas where it could not be seen:

> "Well one of the nurses, when I came in for them to have a look at it, one of the nurses she noticed, 'Do you know you've got a blister on your heel?' I said, well I know there's something there but I can't see my heel and she said, well you want to keep an eye on it. And from that it started going black and nasty" (patient 10: 49).

A theme running through the interviews relates to 'attributing blame' for the development and cause of the pressure ulcer. For some patients there was no one to blame:

> "I can't blame anybody. It's just one of those things" (patient 11: 115).

Some patients attributed the development of their ulcer to another condition, for example multiple sclerosis or a neurological condition causing decreased activity. As such, they were 'susceptible' to ulcers:

> "Yeah I hope I don't get anymore like, but I suppose I'm suspect (*sic*) being somebody who's sat in a wheelchair and conditions, you know" (patient 1: 162).

This susceptibility was also attributed to feeling in poor health or to a loss of appetite and decrease in weight due to poor condition. Diet was highlighted by patients as important to the healing and prevention of pressure ulcers but that often their condition decreased their appetite:

> "They say when you get those pressure sores, well when I went into hospital, I was in [name of hospital] and I felt that lousy I just didn't want to eat. So you're in a decreasing circle, if you know what I mean" (patient 1: 126).

Diet was referred to by patients who suffered with diabetes and these patients recognised that once an ulcer developed then the diabetes influenced its healing:

> "I'm diabetic as well which makes them slow in healing" (patient 9: 107).

Three patients blamed themselves for the development of their ulcer. The reasons for this self-blame included not looking after themselves (e.g. incontinent and not washing and drying skin properly), lack of knowledge, ignorance or naivety such that they did not seek advice or treatment:

> "I don't know what went through me mind really. I must have been totally naive. I just thought it [the pressure ulcer] would go away like, you know and all that. But it didn't" (patient 1: 83).

However, other patients specifically blamed healthcare professionals. The reasons for this blaming of others were varied. Some patients questioned whether the ulcer could have been prevented if staff had listened to their concerns, and a few revealed that they had informed staff that they felt an ulcer, but that no action was taken because staff could not see anything:

> "I did say, and I've always been sorry about this, but I don't know whether they liked it or not but I said, 'there's something wrong at the bottom of my back, it's so sore'. Oh well, of course, the doctor said, 'roll her over' and then have a good look at it. Well two nurses said there's nothing to see. So I said, 'well I'm not pulling a fast one, as they say, there's something wrong somewhere.' And so I don't think they took any notice of me, rolled me back and left me in bed … I think if a person says they've got it [an ulcer] I wish the nurses would see to it sooner. It's as if they had to wait until it got really bad before they did anything in my case and I wish that they could have done something, like let me off the sling a bit sooner" (patient 2: 155 and 255).

The delay in thoroughly inspecting skin was commented on by a number of patients, who also commented on the lack of priority attached to their reports of an ulcer to nursing staff:

> "I kept saying my bottom hurts. 'Does it love, oh we'll have a look in a bit' [patient mimics nursing staff comments]. It's as bad as Spain, 'un momento', but here it's a minute and then a minute runs along and along and it was about two or three days when I had this that they came and looked and said, 'oh gosh have you seen this.' Then someone else came and had a look, 'oh dear, we never thought to look there did we, with it being inside there"(patient 19: 43).

In addition, a small number of patients reported that it was not the lack of action by staff that caused the ulcer, but actions by the nurses or treatments given. For example, one patient reported that their ulcer had developed because of an ill-fitting splint:

> "Well I think it [the ulcer] is because of this splint, very bad fitting, very rough edges and it caused a blister on my heel" (patient 3: 151).

In another circumstance a patient described the "persistence" (patient 20: 29) of staff using a hoist to move her from bed to chair. The patient explained that she had asked staff not to use the hoist because she felt her skin being pulled. However, staff did not listen to her and she graphically described how her skin eventually split while she was on a hoist. Other patients also alluded to the use of hoists and the discomfort they experienced when in the sling.

Others questioned whether they received appropriate care in the early days that could have prevented the development of the pressure ulcer. For example, one patient, who was chairbound, suggested that he did not receive a pressure-relieving cushion early enough. Although he accepted that he may have developed an ulcer anyway, he felt that not enough was done to help prevent the ulcer:

> "So as soon as you get pressure sores then the [*pressure-relieving*] cushion comes up on the scene. You know, it's too late. I'm not saying it'll prevent your pressure sores like, but it might have helped!" (patient 1: 318).

This issue was brought up by other patients who were chairbound. The emphasis of these complaints was for increased attention to preventive rather than reactive strategies:

> "The point is, these people at the Wheelchair Centre know I'm in this thing [refers to wheelchair] all the time. They know I'm sitting down all the time They know there's a possibility of getting sores. So they should have been thinking about" (patient 17: 236).

Descriptions of the pressure ulcer

During the interviews, patients described their pressure ulcers. All but two participants (n = 21, 91%) referred to the pain associated with pressure ulcers. Of the two who did not experience pain, one reported having a neurological condition which meant that he had reduced sensation from the waist downwards and the other said they were simply unaware of the ulcers until told by nursing staff:

> "I wouldn't have known, hadn't they put me in the bath at [*name of hospital*]. No they [*pressure ulcers*] haven't hurt me, so that's something … I didn't know until the nurses told me. I had no idea" (patient 15: 83 and 223).

However, the majority of patients reported experiencing some sort of pain, ranging from extreme pain "red-hot poker" (patient 20: 195) or "worse than toothache" (patient 22: 213) to at least a "nasty niggling pain" (patient 21: 137) or "slight sensations … little shooting pains" (patient 4: 135). There was also variation in when pain was experienced. For some patients the pain was constant, whereas for others the pain got worse at night, it sometimes varied from day to day, it increased if hit by bedclothes or would flare up at varying times of the day:

> "It's just there all the time and sometimes you think it's raving up now I'd better move, you know, and you just ease" (patient 19: 87).

The patients used a variety of words to describe the pain sensation that they experienced. These include: shooting, stabbing, jumping, niggling, hot, red-hot poker, carpet burn, tender and raw. Some patients suggested that staff did not fully appreciate the pain associated with the pressure ulcer and felt that their complaints of pain were ignored by staff:

> "I've got more pain now than I had before I came in. I'll tell you the truth. I can't stand it no more that's if they [refers to nurses] bloody take notice of me" (patient 12: 31).

In addition to descriptions of pain, the patients offered other descriptions of their ulcer. These included references to their skin (loose, dead or hard skin), dimensions of the ulcer (cavity or hole, which was shallow, deep or massive), origin of the ulcer (as either coming from underneath the surface of the skin or starting on the surface), first signs of the ulcer (scratch on skin surface, stinging, an itch that you want to scratch, skin irritation, blister or leakage), physical appearance of the ulcer (angry looking, not pretty, raw, black and nasty or bare bone), physical sensation of the ulcer (like a bruise), references to the ulcer being badness or poison in the body, leakage from the ulcer (dripping fluid or blood), smell from the ulcer (terrible, noticed by others, e.g. nurses) and embarrassing:

> "I noticed the nurses were changing the dressings they could hardly stand the smell of it, the smell is terrible. It comes through the whole bandage you see and to me it's an embarrassment" (patient 10: 109).

Patients also commented on the descriptions used by nurses so that patients could visualise their ulcer. These descriptions were graphic, referring predominantly to the size of the ulcer, for example size of a 50-pence piece, able to get fingers in or able to get fist in:

> "The way they've mentioned it in the past is that you can actually put your fist into it and other times you can fit a couple of fingers in it when it's healed up or whatever. So that's the only way I can visualise it" (patient 17: 140).

Many patients described that they were unable to see their ulcer because of where it was located: sacral or heel area. Not being able to see the ulcer was difficult for some patients because this meant they were not aware of their condition:

> "I don't like it [*not being able to see the ulcer*] at all. Because when you can't see it, it's most difficult isn't it?" (patient 2: 291).

However, over half of the patients (61%, $n = 14$) commented that they did not want to see their pressure ulcer, despite being offered ways of being able to see it, for example using a mirror, photograph or video:

> "I don't want to see it full-stop. Just the thought of it puts me off, and where it is" (patient 17: 156).

However, those patients not wanting to see the ulcer described it using language which demonstrated their disgust at having an ulcer, such as "horrible" (patient 11: 67) or "I hate it [the ulcer]" (patient 14: 19).

The impact of developing a pressure ulcer

All but two patients ($n = 21$, 91%) indicated that the pressure ulcer had impacted on their lives. Those who felt the pressure ulcer had little impact were the patients who had a road traffic accident. These patients had multiple injuries and fractures, and so the ulcer was relatively unimportant. One patient who had experienced a fractured pelvis, hip joint, femur and ankle following an accident recalls:

> "The sore has had no impact whatever since the beginning. If the nurse hadn't told me I'd got one, I shouldn't know I'd got one. So it's had no impact at all" (patient 4: 167).

However, the ways in which the pressure ulcer did have an impact were described by other patients. These included emotional and mental, physical and social impacts.

Patients described varying levels of preoccupation with their ulcer. At one end of the continuum patients did not think about their ulcer and expressed that it was the least of their health concerns, while at the other end of the continuum some patients had high levels of preoccupation, anticipating pain whenever they considered moving their position, worrying that they would not be able to get rid of the ulcer or worrying that it would get bigger:

> "Well I suppose you do have some concerns whether they're going to heal up or whether they're going to breakdown in the future, don't you?" (patient 13: 115).

Some patients described how they coped with having an ulcer by putting up with it or adopting an 'out of sight, out of mind' approach. However, others described hating their ulcer and trying to distract their attention away from it by "not thinking", "not dwelling" or "forgetting" the ulcer and "keeping busy". The emotional impact for some patients was therefore significant. Aligned with these coping mechanisms were perceptions about what having an ulcer meant for the patients. For patients who expressed preoccupation with their ulcer they also described its impact in a number of ways. Some patients stated that the ulcer was an added complication to their health and had created a setback to their recovery:

> "Sometimes I feel annoyed, very annoyed, that something else [*refers to pressure ulcer*] has come, you know. Sort of put a spoke in the wheel shall we say. And just when you seem that this was improving, well back down again. That's how I feel" (patient 10: 69).

> "If this [*refers to pressure ulcer*] hadn't have developed I would have been all right. I would have been walking smashing" (patient 16: 147).

Other ways in which the ulcer impacted on patients were that it made them feel depressed or miserable and, for some, decreased their confidence. For some patients the pressure ulcer was preventing them from being discharged from hospital or was the reason for admission. However, for some patients this was a shock:

> "I didn't know, I thought you just deal with it [*refers to pressure ulcer*] at home like, but it was that horrendous I had to be hospitalised" (patient 1: 95).

The pressure ulcers were referred to as troublesome, a nuisance, annoying, disruptive or an inconvenience. Many of the patients referred to their increased dependence on others to treat their ulcer and to keep them informed about how it was healing. Sometimes this could lead to frustration because the patient's opinion conflicted with that of the professionals:

> "The nurses come and have a look at it and they go, 'well it was better than what it was yesterday.' I say, well it doesn't feel it!" (patient 16: 255).

The treatment and management of pressure ulcers and the impact of this on patients are described in the next two sections.

The pressure ulcer had a physical impact for some patients. First, it affected their positioning and comfort. Patients with a sacral ulcer reported difficulties associated with sitting in a chair and keeping pressure off their sacral ulcer. Many of these patients were positioned in bed on their side but found this uncomfortable. They reported that it was difficult staying off their ulcer, that moving position was often painful if they rolled over, and that other limbs became painful because they were adopting positions to protect their ulcer:

> "I have to lay on my side for as long as I can bear, because actually my arms begin to ache for a while because laying on your side you can't do anything" (patient 20: 135).

The issue of comfort is picked up in a later section when considering the treatment and management of pressure ulcers.

Second, the ulcer limited or affected patients' activities. Patients reported ADL that were limited because of the ulcer. These affected activities ranged from moving from bed to chair, requiring assistance to move limbs affected by an ulcer, showering, carrying out exercises, using the toilet and not being able to go shopping or carry out housework:

> "[*The ulcer*] is under stress and I have to take a deep breath, I'm telling you this very frankly, I have to take a deep breath to force myself to pass the motion past my sore bottom" (patient 20: 171).

While not being able to go to the shops limited patients physically, it also has a social impact on them because they are not meeting people outside their home. However, one of the younger patients also referred to the social impact of the ulcer on her life because the ulcer limited her choice of footwear owing to the pressure put on to the ulcer by shoes:

> "I can't wear any shoes or proper slippers. I'm stuck with these mules because that way I haven't got any pressure on the back of my heels … the only time I wear proper shoes is if I'm going out anywhere and because of my immobility I've no intention of going anywhere anyway. So it's like a catch 22 at the moment … If I'm going round shopping they [mules] are no use at all. I prefer to wear shoes … and apart from that you don't go shopping in slippers!" (patient 3: 251).

The pressure ulcer also had a medical impact on some patients, which had physical consequences. The two main medical impacts of the ulcer were infection and surgery. Patients reported pressure ulcers that became infected; one patient (patient 1) developed a bone infection because of the depth of the pressure ulcer and had subsequent amputation. Patients reported feeling unwell because of their pressure ulcer:

> "November last year, I didn't feel too well because the pressure sore had got infected and I just felt really ill with it" (patient 17: 91).

Patients' experiences of pressure ulcer treatment, management and care

Dressings and treatments

Dressings played a big part in the discussions with patients about pressure area treatment and care. Patients mentioned a variety of dressings and treatments used to help the healing of their ulcers and, in their words, these include foam, gel, padding, bandages, spray, plasters, vacuum-assisted closure (VAC), iodine dressings, dry dressings, cleansing and debridement. The patients' experiences of dressings were variable: there were no patterns in the data related to experiences and age, gender, chronic or acute condition.

Some patients reported that having their dressings changed was painful. The pain experienced originated from a variety of sources. For some it was the pressure ulcer itself that was tender and therefore caused pain. For others the pain was caused by the staff not being careful in their approach, and patients describing dressings being "whipped off" (patient 20: 227) or removing hairs. Patients also described the dressings as sticking to their skin because of the adhesive, which made it difficult and painful to remove and could tear their skin:

> "Now I had a big plaster on there at the beginning and at the beginning it was getting done twice a day and I had to tell them to stop it because I couldn't stand it. It was tearing my skin off because the skin at the top of your legs is very thin" (patient 8: 83).

Other complaints about dressings were from patients who had an allergy to a particular dressing which caused discomfort. Discomfort was also experienced by patients when dressings started to come off and 'ruffle' over the ulcer or where the wrong size dressing was applied (when too small the ulcer would leak fluid):

> "I don't know whether it's my pressure sore or if it's the dressings that they're putting on but they actually

> leak quite a lot. And because they get wet, they come unstuck and they actually come off regularly. Which means I'm having to get my dressings done about 2 or 3 times [a day]" (patient 17: 248).

A younger patient criticised the skills of some nurses putting on dressings. He suggested that dressings came off because they were not put on correctly in the first place. When the dressings were too big they were described as uncomfortable and getting in the way of activities such as toilet use:

> "She [*nurse*] said 'I'm going to put you something much smaller on and hope it won't interfere with anything else' [*referring to going to toilet*]" (patient 2: 287).

For other patients, dressing changes were not painful and some reported that having it done increased their comfort, eased their pain and "sucked out" infection, so they looked forward to them being changed. Many patients used the word "lovely" when referring to dressings being changed:

> "It feels lovely once she [*nurse*] has got it [*dressing*] off, you know, when it's ready for re-dressing. It's lovely" (patient 9: 199).

Some patients commented on staff being "very careful" (patient 13: 91) when changing dressings.

The time devoted to treatments was a significant theme across the interviews. While some patients indicated that they welcomed their dressing changes (discussed above), for others the time taken for this activity caused inconvenience, with some patients reporting that dressing changes could take an hour, and another being admitted to hospital for 5 days of VAC therapy. In the community, patients reported having to wait at home for district nurses, which prevented them from going out. For other patients, the inconvenience (and disruption) was being admitted to hospital with an ulcer that could not be treated in the community: "It disrupts your life because I'm spending time in hospital" (patient 17: 176). However, many patients resigned themselves to treatments and described "putting up" with them:

> "Well I just put up with it like. Because you know, you think well you're getting better like" (patient 1: 186).

The timing of treatments was also commented on by patients and this has been discussed in the section on attributing blame, where patients considered that treatment was given too late or that more preventive strategies should have been used with patients susceptible to pressure ulcer development.

Pressure-relieving equipment

Equipment used in the treatment of pressure ulcers included specially designed mattresses and cushions. The patients' experiences and perceptions of these were, again, variable. These related to issues of comfort, safety, availability and timing.

There were wide variations in patients' reports of mattress comfort. Some patients did not find the mattresses comfortable: "These [*beds*] are neither use nor ornament really when you think of comfort" (patient 19: 171), whereas others found them very comfortable, one patient commenting the mattress was like "somebody cares" (patient 20:87). Reasons given for lack of comfort were that the mattress could restrict movement making it difficult to reposition in bed, and that the mattress was noisy:

> "But they've actually just changed it [*the bed*]. I was on a different one before but it was sort of making, the box at the end of the bed was making a few noises" (patient 17: 160).

There was less discussion of comfort in relation to pressure-relieving cushions, partly because not many of the patients had one. This was also the case for patients who were chairbound. One commented on the fact that patients used to be provided with a rubber or air-filled ring when sitting out in chairs, but that these were no longer available (patient 19). However, another commented that an air-filled cushion on their chair made them feel unsafe:

> "I was finding it difficult to use that one [*cushion*] because where you put pressure on that one it deflates, sort of air moves about in that other cushion. So if I sit forward in that other cushion, where I'm sitting down, it goes down and I felt unsafe, I felt like I was going to fall out of my wheelchair" (patient 17: 51).

Patients who were chairbound criticised the lack of availability of cushions and delays in providing equipment. They had concerns that there was sometimes a lack of attention to preventive measures in pressure care.

Professional attention

Patients reported that the assessment and management of their pressure ulcer in hospital

and the community involved a variety of professionals, including doctors, nurses and physiotherapists, and other caring staff such as home carers. Overwhelmingly, patients referred to their dependence or reliance on these people because they required others to assess and treat their ulcers. In some situations, the treatment affected other ADL. For example, a patient having VAC therapy required help to wash:

> "I was laying in bed constantly for 5 days, that's how long I had it [VAC pack] on for… but because when I've got it on I can't sit up. So I was laying in bed on my side all the time. I was having to eat and drink on my side. I couldn't do anything for myself. The nurses were having to wash me" (patient 17: 107).

In particular, having an ulcer meant that patients required help from nursing staff, or other carers, to help them to move into a comfortable position and to alternate the pressure on vulnerable areas of their body:

> "As I am now, I can't turn over and I'd been on my back quite a lot and I did try to turn over once or twice but it's very, very difficult and I can't really do it on my own you know" (patient 13: 43).

Some older patients commented on the negative attitude of some nursing staff when asked to help with turning a patient. It was perceived that nurses did not like helping with this activity and that it was carried out at the convenience of nursing staff rather than at a patient's need. For example, some patients wanted help to stand during the day or to move using crutches, but this was ignored and staff would use a wheelchair for convenience rather than helping a patient to stand and walk. Patients attributed this to the wards being short of nursing staff. However, some commented that they were not moved during an entire shift:

> "My morning is breakfast, round about 10 o'clock. Then they wash me, I have a bed bath. Then I'm helped out of bed onto the chair and I sit here until I go to bed at night, round about 7 o'clock in the evening. Other than that I get no help at all" (patient 22: 151).

At the other extreme, some patients reported on staff religiously turning them in bed during the night shift. So much so that they felt exhausted because their night's sleep was disturbed: "Used to turn me every night, every hour … I was shattered next morning" (patient 6: 247).

Patients' dependence also related to them relying on others to keep them informed about healing. Many of the older participants had "faith" in the nursing staff to heal their ulcers: "They [nurses] know what they're doing" (patient 13: 79). Only one younger patient criticised nursing staff for their lack of skills in the use of some equipment. For example, VAC therapy:

> "Plus half the nurses don't even know how to work it [VAC]. So if I need to go to the toilet, they're not going to be able to disconnect it or anything" (patient 17: 224).

The position of sacral and heel ulcers meant that it was difficult for patients to see them. Some patients reported professionals using expressions to help them visualise the size of the ulcer (described above); however, more specific information about the pressure ulcer and healing was often lacking for many of the patients. Professionals used general expressions such as "it's all right" or "getting better":

> "I mean they [*nurses*] don't tell you a lot. Each time I've said what's it like? – 'Oh better, getting better.' So I take their word for it" (patient 2: 299).

Some of the older participants also reported that they could not understand some of the advice given to them about their pressure ulcer because it was not specific enough or did not make sense to them:

> "Because that's the trouble with pressure sores. They say keep off them but that's why they happen because you're on them, you know, your most vulnerable spots like. So it's difficult to keep off a pressure sore" (patient 1: 166).

In some situations conflicting advice was being provided by different professionals. A patient with an ulcer on their heel comments:

> "… but I still have to put pressure on my foot to lift myself up, you know. So the doctors don't want me to put any pressure on my foot, physio has said that I have to, so it's just a vicious circle really" (patient 16: 167).

Younger participants reported frustration that there was a lack of advice at the outset related to the length of time that it might take for an ulcer to heal:

> "Nobody actually come out and said, 'Oh it'll take this long to heal', else you would have gone bananas like! But it's sort of, I don't know, you just drift on like from week to week with them" (patient 1: 218).

Patients' reflections on the longer term impacts of pressure ulcers, and the development, treatment and care of their ulcers

Follow-up interviews were conducted at 3 months with a small group of patients (7/23, 30.4%). These follow-up interviews offered an opportunity for the patients to reflect further on the longer term impact of the ulcer on their health and quality of life, as well as the development, treatment and care of their ulcer. The content of these interviews revealed similar themes and patterns related to whether the participant had faced an acute event or was experiencing a chronic condition. Despite the time between first and second interviews, three new areas were to emerge within existing themes from first interviews. These new areas related to the themes of diet, ulcer healing times and professional descriptions of the ulcer.

Diet was referred to at first interview in terms of how a reduced appetite or dietary conditions, such as diabetes, affected the development and healing of an ulcer. At follow-up, three participants referred to advice that they had been given about diet and how this would help the repair of their ulcer. In particular, the patients recognised the importance of protein in their diet for healing: "I eat plenty of protein" (patient 1, follow-up: 131). The following quotations imply that the dietary advice was given while they were in hospital, but they had not raised this at first interview:

> "Oh yes they did put me onto full cream milk, I had a dietician while I was in hospital" (patient 15, follow-up: 115).

> "No and since I've come home, I'm still on my milkshakes [*dietary supplements*]. I still have them, two cups of that a day" (patient 11, follow-up: 130).

Time associated with treatment (including waiting for a healthcare professional to visit for dressing changes) and healing of pressure ulcers were raised at first interview. At second interview, two of the participants re-emphasised the length of time that it was taking for their ulcers to heal. One was surprised at the reality of the length of time for healing, while another commented that it had taken longer than advised:

> "[*The doctor said*] it's going to be 12 months before it heals up and things. I just thought he was joking, but evidently not" (patient 15, follow-up: 83).

> "So it did take a bit longer than the 3 months to what he [*the doctor*] said" (patient 11, follow-up: 58).

One further participant (patient 4) reported that he had gone on to develop a sacral ulcer. At first interview he had an ulcer on his heel and reported that this had not caused him much of a problem. However, he indicated that the sacral ulcer was more painful and problematic for him, and had resulted from lying in bed in hospital following a road traffic accident:

> "I was still obviously spending a lot of time in bed and I did develop soreness and quite bad soreness in my bottom from lying in bed presumably? Now that was treated regularly by the nursing staff with an ointment that had an iodine base or something and at times that was far more painful than the actual bedsore that we're talking about on the heel" (patient 4, follow-up: 129).

First interviews revealed that many patients were unable to see their ulcer because of its location (sacral or heel), but also their lack of willingness to see it. Patients relied on professional descriptions of their ulcer, but at follow-up a small number of them questioned whether the language used was appropriate. This is because on reflection the participants revealed that these descriptions depicted a horrific image of their ulcer:

> "The way people described it to me, it just made it sound horrific. I mean you're talking about a 3 inch hole and you can put your fingers down to the bone. And to me that's horrific" (patient 11, follow-up: 66).

In general, although the second interviews were limited in new content, they still proved useful for expanding some of the existing themes. However, in over half of the follow-up interviews it was difficult for the interviewer to keep the focus on the participants' pressure ulcers. The participants had moved on from their hospital experience and their pressure ulcer, and other issues now took priority for them. In three of the interviews, participants described adaptations to their houses that were not related specifically to the ulcer. A further participant was not interested at all in discussing her past pressure ulcer. Following discharge from hospital, she had experienced repeated falls and she wanted to discuss how this had made her feel unsafe in her home and caused her to lose confidence carrying out daily activities. These topics dominated the interview. However, another participant focused entirely on his pressure ulcer, and demonstrated the longer term anger and resentment that can be associated with the treatment and care provided for pressure ulcers. At first interview, this participant blamed healthcare professionals for the development of his ulcer, and felt resentful about his dependence

on others for treatment and for help with ADL. He raised the same issues during the second interview, displaying sustained anger related to his pressure ulcer.

Limitations of the substudy

Recruitment of patients

The nurses on the trial wards were effectively the gatekeepers in the study. The CRNs only knew of people not recruited to the trial who had pressure damage if the ward staff informed them. On one occasion, the researcher arrived on a ward to interview a patient and the ward staff indicated that the patient's pressure ulcer was not regarded by them as a pressure ulcer, rather they described it as a non-healing graze (on the buttocks). The CRN had checked the position, visually inspected the ulcer and confirmed (after the interview) that the open area was classed as a pressure ulcer. If this under-reporting of pressure ulceration occurred in other wards then obtaining information on people with pressure damage could be unreliable. The use of pressure damage as a 'key quality indicator' for care may exacerbate reluctance to describe skin damage as 'pressure ulceration'.

Patient representativeness

After 20 months, 21 patients had been recruited to the study. Only three of the participants at this stage were male. The TMG wanted to address this imbalance and recruit more male participants to the study. Therefore, in the final 4 months of patient recruitment (after 21 people had been interviewed), the group asked nurses to notify them of any male patients who were potentially willing to talk to a researcher about the pressure ulcer. A further two men were interviewed during this period.

A potential reason for this imbalance could have been if the population at risk of pressure ulcers was predominantly female. To check this, the TMG asked the trial statistician to report whether there was an imbalance in the genders recruited to the trial. This analysis of the people recruited to the PRESSURE Trial confirmed that there were more female patients than male patients (64% versus 36%).

Second interviews

The original plan was to see participants at home up to 3 months after hospital discharge, to ensure that information was collected on experiences with pressure damage after an acute period of illness, to capture experiences of ulcer healing and to collect reports of experiences away from the hospital setting, in case patients wished to comment on any aspect of their care.

Interviewing people after discharge from hospital created difficulties. Of the first 17 people interviewed, five failed to reply to two letters offering a home visit for the follow-up interview; three had died in the follow-up period, one declined a follow-up interview and one was only located at a new address once they were well over 3 months postdischarge (that is, 'out of time'). This meant that only seven follow-up interviews at home were carried out. Given the poor rate of obtaining second interviews, the researchers examined the potential for increasing the sample to include people treated at home with pressure ulcers.

At a TSC meeting (June 2003) it was recommended that, owing to the problems obtaining follow-up interviews, sampling for the qualitative aspect of the trial should capture experiences of people in the community as well as in hospital, by recruiting people with pressure ulcers in the community. An extension was sought to the qualitative study to allow the researchers to approach such people, to interview them about pressure ulcers and the impact that they and their treatment were having on their quality of life. As the MREC felt that a full ethics committee application would be needed to extend the scope of the study to people in the community, this was not pursued owing to insufficient resources and time to reapply through MREC and other research governance procedures.

These methodological issues were reported to the TMG and TSC as progress reports. By the end of recruitment to the qualitative aspect of the study, seven out of 23 people were interviewed at follow-up visits, one person declined, one changed address, three had died, nine did not reply to the letters and the final two patients were not approached because of time constraints.

Summary

This study explored how patients with pressure ulcers perceive and describe their health and quality of life, their experiences of developing a pressure ulcer and their experiences of pressure ulcer care.

The development of a pressure ulcer has physical, emotional, mental and social impacts. In addition,

TABLE 58 *Summary of the study findings*

Research objective	Theme	Subtheme (first interview)	Subtheme (follow-up interview)
To explore how patients with pressure ulcers rate their health and quality of life	Contextual detail	Age Chronic condition Levels of dependence Living arrangements	
To explore patients' experiences of developing a pressure ulcer	Perceived cause of ulcer	Level of mobility Dependence to move Bed/chairbound Skin condition Shearing pressure in bed Delay noticing ulcer Delay treating first signs Poor health Poor diet/appetite Lack of knowledge Actions of another 'Susceptible'	Dietary advice
	Descriptions of ulcer	Pain Skin condition Dimensions of ulcer Origins of ulcer First signs of ulcer Physical appearance Physical sensations Poison Leakage from ulcer Smell from ulcer By professionals Unable to see ulcer	Inappropriate
	Impact of ulcer	Lack of impact (acute) Emotional Mental Physical Social	Development of second ulcer
To explore patients' experiences of pressure ulcer care	Dressings/treatments	Variety Painful Staff approach to care Allergies Poorly applied dressings Disruptive Time consuming	Length of time to heal
	Pressure equipment	Mattresses Cushions Variable comfort Safety Delay in provision	
	Professional attention	Variety involved Reliance on professional Attitude of staff to care Poor information Conflicting information Lack of advice	

the development of a pressure ulcer can be pivotal in the patient's trajectory from illness to recovery, with the development of an ulcer preventing them from making a full recovery and causing varied impacts on their quality of life. The patients also revealed their perspectives on the development of a pressure ulcer, their experiences of having an ulcer, and the ways in which ulcers are treated and managed. This reflected variation in patients' experiences of an ulcer and variations in levels of dependence on others to treat, manage and care for them. The findings from this exploratory study are summarised in *Table 58*.

Analysis of the interview transcripts ($n = 23$) achieved saturation. The understanding gained from these findings may be transferable to other groups of patients and settings.[71]

Chapter 6

Results of the focus group substudy

Baseline data

Nine CRNs, from five trusts (representing nine of the 11 research centres), participated in the focus group discussion. Over half of the participants ($n = 5$) were from one NHS trust (with four participating research centres), three of these CRNs were no longer in post: one had moved into another research post (not related to pressure care) and the other two had returned to nursing practice as ward sisters. Despite strong representation from this one trust, this did not appear to affect the group dynamics adversely. CRNs from each of the participating trusts contributed to a lively discussion (lasting for 1 hour and 40 minutes). The group was not dominated by any individual or trust.

The CRNs reported extensive clinical experience (with varied backgrounds in elderly care, orthopaedics, theatre and intensive care nursing) and an interest in pressure care, many taking a lead on pressure care and tissue viability in clinical areas before their CRN role. Five of the participants also reported that they had completed some form of formal research training (such as a diploma or degree) which had informed their role as CRN.

To maintain anonymity of the focus group participants, each CRN has been given a number (1–9). However, where there is discussion between members from the one trust (represented by five CRNs), the CRNs have also been labelled a–e. This ensures that later quotations are not easily linked to CRNs from this one trust.

Findings

The focus group offered an opportunity for the CRNs to share both their experience of their role and observations of pressure ulcer prevention; some observations were specific to the trial, whereas others were about general care. The discussion among the CRNs was lively and, although there were no dominant participants, it was evident that participants working in the same centre referred to each other during the discussions to reinforce some of their observations. One example of this was when three CRNs discussed ward staff hostilities and the resulting difficulties encountered in one of the centres. One of the CRNs (CRNd) has left their post:

> CRNd: "There was times when we felt that we had to support each other by going together [*on to the wards*]. We didn't really need each other for any other reason than to hold each other up! It's your turn to stand in front this time! [*Laughter in the group*]. Sometimes it could be like that but yet it was amazing how much people could change. You know, we had times when we went onto one area and we would hold hands and then we went and it was like – 'wow' – and suddenly the whole atmosphere, the whole thing had just completely changed."
>
> CRNa: "And that's strange that because I know from what, well, I still have a problem in that area that you're referring to. Even now, after all this time, going regularly, daily to that ward, I still have an issue going to it."
>
> CRNd: "It's interesting because it was completely different one day, it was one day where we had gone and then we came back to the office and went, oh my god, is this the same person, that was almost normal, and in fact I've got gifts here! And everybody was saying are you talking about the same person, and I said yes, can somebody come with us tomorrow because I'm not quite sure! [*Laughter in the group*]. And it was really strange how it just literally seemed to be one day it just went from holding each other up to not being an issue anymore – for me. It's really bizarre."
>
> CRNc: "I noticed a difference because I don't very often go to that area, you know, from when I first started and between now. So there's a huge shift and it's been sustained, I'm pleased to say."
>
> CRNd: "Oh has it?"
>
> (Discussion among CRNs from the same trust, focus group, March 2004)

In addition, two further participants from the same centre discussed some of the early challenges associated with setting up the trial and with developing materials to increase staff awareness of the study. Throughout the focus group these two CRNs referred to each other when making statements, reinforcing their points of view and asking for each other's opinion on matters. Take the following example of dialogue between them,

noting the use of 'we' to refer to their early efforts establishing the trial:

> CRNa: "We did the"… [*looking to CRNe*]
>
> CRNe: "… teaching package, didn't we?" [*reinforcement by CRNa*].
>
> CRNa: "But on a daily basis as you visited the ward, you talked to the nurse. If the forms weren't filled out, and often they weren't, so you talked to the nurses involved. Who was on that team? And you used to ask them 'Are you okay in filling these in? Do you understand them?' You know. So you had your daily contact. But initially we went round every ward and we did the teaching session."
>
> CRNe: "We had articles of research to help them understand what qualitative, quantitative, good pressure care."
>
> CRNa: "We put a file together with all these articles in, all these packages, and you would say 'Have you looked in your package?' You know. We had the problem solvers for the mattresses and a year down the line, you would be saying to the nurses 'Have you looked at the file?' And they would say 'Oh I didn't know that was there!' But you address things on a daily basis and the dissemination of knowledge would be constant. You were constantly 'Are you sure?' Yeah. Reassuring."
>
> CRNe: "And then every 6 months we did the flyers [*about the research*] to update them where we were, how many we had recruited, you know. We never identified areas of …"
>
> CRNa: "We had the website. So there was quite a lot of work actually put into the actual initial setup to help them with their understanding. But it wasn't always ..."
>
> (Discussion among CRNs from the same trust, focus group, March 2004)

These two participants were recognised by other participants as leaders in the trial because of the work that they did at the outset and because of their involvement in developing and establishing pressure care guidelines:

> CRNc: "[*Names CRNa*] you were involved in the guidelines weren't you?"
>
> CRNa: "Yeah. Guidelines for the Trust leading out of the NICE guidelines. So we had all the people in the right places really making sure that we were updated because we had to keep our credibility. We had to be seen that we were updating things and moving on" [*looks to CRNe*].
>
> CRNe: "We got the NICE guidelines. We got them sent and we distributed them to the wards."
>
> (Discussion among CRNs from the same trust, focus group, March 2004)

Despite the time constraint, the aims of the focus group were covered. However, analysis reveals two general areas missing from the focus group discussion. First, CRNs focused primarily on negative or poor practices, despite the facilitator reinforcing the need for CRNs to focus on both positive and negative practices. Second, CRNs did not address the treatment of pressure ulcers and in particular the use of dressings. They tended to focus on prevention or other care, such as patient positioning. Follow-up telephone interviews were carried out with a small number of CRNs to address these gaps. This is summarised in appropriate sections in this chapter.

The focus group findings are presented under the three themes presented to the CRNs for discussion:

- general experiences of being a CRN
- observations of pressure care related specifically to the PRESSURE Trial
- general observations of pressure care in clinical practice settings.

General experiences of being a CRN

CRNs were keen to share their experiences and stories associated with their role. These fall into three main categories:

- adapting to a new role
- setting up and running the clinical trial
- maintaining motivation during the clinical trial.

Adapting to a new role

All participants were in agreement that their role as a CRN was very different from their role as a ward-based clinical nurse. The ways in which the CRNs experienced such change varied by participant, ranging from "marvellous" (CRN3) to "I was in tears, thinking what have I done?" (CRN8). There were key issues influencing the nurses' transition from ward-based clinical nurse to a CRN (e.g. working on their own, with subsequent feelings of loneliness) and therefore influencing the time taken by individuals to adapt to their new role. Importantly, all of the participants described some initial loss of confidence:

> "I felt that I was fairly confident in the job that I had and then felt extremely like a novice" (CRN7, focus group, March 2004).
>
> "I lost a lot of self-esteem and professional esteem at that time and had to think very long and hard about whether I would continue" (CRN8, focus group, March 2004).

The CRNs attributed this initial loss of confidence to learning new skills for their research role and adapting to working across clinical areas with a variety of professionals. Associated with this change in role was having to adjust to working on their own. A number of CRNs referred to the research role as a "lonely" experience. This was exacerbated by the lack of practical support offered by many of the trusts in the early days of the trial (some CRNs struggled to find office space and computers) and also by the fact that they felt that they were perceived as a minority group. Many other nurses working as researchers in the trusts were assigned to medically-led research. This increased their sense of isolation as nurse-researchers. However, little insight was provided into why the two research roles were viewed as so different. Working on their own was also described by some CRNs as a stressful experience:

> "One of the things that I found was that I had been part of a big team. And although we were still part of a team with the trials unit, and all of us across the North of England, we were very much more autonomous and had to plan and think for ourselves. And that sort of was quite strange really" (CRN7, focus group, March 2004).

Stress arose because they found themselves in a position where they had to make decisions associated with an unfamiliar role, without the support of colleagues. Some worried about failing in their new role:

> "Being on my own and as [*names CRN7*] said being autonomous, I've got to make these decisions myself, I've got nobody else to – I mean yeah you have other people around you, but the fear of failure to, the fear that you're not going to match up to the job, you know, that you've been put in post to do" (CRN8, focus group, March 2004).

Time taken to adapt to the CRN role varied by individual, but overall it appeared to be relatively short, with CRNs reporting that they adapted and gained confidence in their new role within a couple of months. During the follow-up interviews, both CRNs were keen to emphasise that they had enjoyed their role and had gained both personally and professionally from undertaking it. They were keen to reinforce that the role was, on the whole, more positive than negative and that, following the focus group, they had concerns that the group discussion tended to focus on the negative aspects. One CRN commented that she would not have worked throughout the trial period if she had not really enjoyed the role (CRN 4, follow-up, July 2004).

However, there was an ongoing tension for the CRNs during the trial. This related to their role as both a CRN and a WN. As one CRN pointed out, being a registered nurse with associated professional accountability meant that sometimes this has to take precedence over the research role:

> "I think with professional accountability – if you've got some expertise, and you're asked, you have to intervene [nodding from other participants]" (CRN8, focus group, March 2004).

An example of intervening in care can be seen in some of the accounts given by the CRNs. A CRN recalls how she observed a patient with a pressure ulcer sitting in a chair, without any pressure-relieving equipment, for extended periods. The CRN felt that she had to challenge this care:

> "I went in to a team meeting and said, why is this lady sitting in the chair? I knew she had pressure ulcers, and they said, the surgeon says we have to do it. [*I asked*] who is her surgeon? So they gave me the name of the surgeon and I said I'll speak to him. So then I went and found the physio and said, is there any reason why she has to sit in the chair? None at all. Then we found some evidence. There is some research evidence about sitting people in chairs. Brought all this up [*with the surgeon and nurses*] and the result was that this lady did not have to get up and sit in a chair that she was so uncomfortable in. And her pressure ulcers healed and she went home ... As long as I document my opinion as a registered nurse, not even as a clinical research nurse, as a registered nurse, they're quite happy because they know that I'm on the ward and I'll be a visible presence on the ward." (CRN8, focus group, March 2004).

In examples such as these, being a registered nurse was an important influence for the participants when challenging patient care.

CRNs also reported that nursing colleagues approached them as 'problem-solvers' for issues related to pressure care. CRNs accepted that they may provide specialist advice to WNs, and at follow-up one CRN stated that supporting nurses was an important part of her role (CRN4, follow-up, July 2004). However, some CRNs felt that there was an over-reliance on them to deal with aspects of pressure ulcer prevention issues that should really be dealt with by their nursing colleagues, such as difficulties with pressure-relieving equipment:

> "[*T*]hey seem to think that every problem on their ward about the mattresses is yours, even though we might have one mattress and one patient involved

[*in the trial*]. They're waiting for you when you go on in a morning to tell you that the mattress has bleeped all night long. So you say, well what have you done about it? Nothing! Or they've rung the man [*supplier*] out and he's come and put the CPR stopper back in. That's a big popular one isn't it! [*Laughter and agreement in the group*]" (CRN4, focus group, March 2004).

Being perceived as an expert meant that the CRNs felt pressure to keep up to date with developments in pressure ulcer prevention, and to be seen by their nursing colleagues as pushing forward these developments within the trusts.

Setting up and running the clinical trial

There was general consensus among CRNs relating to difficulties in persuading staff to comply with the clinical trial. These difficulties were encountered while setting up the trial, for example gaining consent from trust ward managers, but then having to maintain daily contacts to remind staff, and raise their awareness, of the trial. In one centre, there had been particular difficulties associated with gaining consent from consultants:

"I hadn't realised how frustrating it was just doing simple things like trying to get consents from consultants. The ward staff it wasn't too bad, but consultants – they just wouldn't answer the letters, they denied ever receiving them" (CRN4, focus group, March 2004).

However, this was not a difficulty widely reported by CRNs working at other centres. In addition, one centre focused on the resources that they had developed to support the profile of the trial: website, research files, teaching packs and research flyers. This was not reported by CRNs working in other centres.

A situation more widely experienced by CRNs was that trust staff would consent to taking part but then did not comply with the study protocol or complete the trial paperwork:

"It was also frustrating when they [*the trust*] agreed to, and allow you, to take part in the trial. But then they would not comply or work in the way that they should be working with you in the trial and say 'Oh yes well we've agreed to do this but, well you know, we haven't managed to fill the forms' or 'We haven't managed to do this!' So that was very frustrating. Yes they were quite happy to take the trial mattress as a sort of sweetener but then 'Oh well we don't know where it is! We haven't got anything to …' – you know" (CRN9, focus group, March 2004).

It was suggested by CRNs that perhaps there was a lack of consultation about the trial between ward managers and ward staff. CRNs viewed consent from the ward managers without this consultation as contributing to a lack of compliance and poor trial paperwork returns:

"I've certainly seen a lot of issues. That the ward manager's agreed, I think maybe without discussing it with the staff – are you prepared to do – and took the consent on for the ward. But then the ward staff really in many, many places have not abided by what we were asking and the returns have been appalling" (CRN1, focus group, March 2004).

An additional explanation offered for poor compliance and returns was offered by CRNs in all centres: that the study created extra work for ward staff and was perceived as "another thing to do".

"… they (ward staff) were so objectionable at times 'We can't possibly do this because it's more work.' But all of us (CRNs) had come from a clinical background and we appreciated that. But when you tried to say to them 'The most you'll have is two or three patients at any one time involved in this, and you're doing the assessments anyway, and we're just asking you to do it a different way.' They still wouldn't take that on board. It was just very much another thing that they had to do and that came across loud and clear from a few wards and … that still comes down doesn't it [*name*] as something that crops up" (CRN1, focus group, March 2004).

Many of the CRNs suggested that this animosity from ward staff created difficulties for them in running the clinical trial. All participants discussed having to deal with 'difficult' characters or 'difficult' wards. 'Difficult' referred to the lack of ward staff compliance with the trial (such as completing paperwork) or the reactions of individual ward staff to the research project and subsequently the CRNs. Importantly, there was some disagreement among CRNs about the predictability of ward participation in the study (within centres). Some CRNs suggested that they knew which wards and staff would or would not participate, while others emphasised unpredictability and change over time, depending on individual ward staff and wider organisational issues:

CRNb: "I am in [*centre X*]. I mean not every ward by any means, I know which wards are going to play ball with me and it works accordingly."

CRNd: "But do you also think like some of the wards that we had, that didn't get very many patients, would fill in every F10 [*trial pro forma*]. Like if you've got a ward with maybe only two or three patients in the time that I worked there, they filled out every single

line. But yet there was some that filled them in every day and that was quite interesting."

CRNa: "Now I disagree with you there. I think there was time when there were wards that had them regularly, they knew what they were for, they knew what they were doing and they did them and yet there was areas that I came across that had wards and you were having to explain it every time you went on because there was no continuity of staff. So it was always 'Well I was only on this morning!' 'Oh well they'll do it this afternoon!' And that sort of thing. And I think it varied quite a lot really on how good they were. And we've even seen a ward that was very good at one point deteriorated rapidly and has suddenly improved again in how they fill the forms in. So it depends on."

CRNc: "I think it's been influenced by wider issues though as well."

CRNa: "Yeah it is."

(Discussion among CRNs from the same trust, focus group, March 2004).

However, overcoming these difficulties was an important challenge faced by all the CRNs.

There was group consensus that a way of overcoming such difficulties was to be seen to help out in the ward areas. By doing so the CRNs felt that they gained the cooperation of the ward staff:

"We would call it diplomacy but it's just manipulating things! If you go and do the obs on a ward for them, they do the skin text. And I'm doing it [*helping out*] to get the skin text. And I'm not doing it to help them out! They think I am!" (CRN5, focus group, March 2004).

The CRNs reported that they invested time in developing relationships with ward staff because they were often made to feel like 'outsiders'. CRNs felt like outsiders because ward staff avoided them when they went on to the wards, "She [nurse] didn't make any eye contact with me [CRN]" (CRN3, focus group, March 2004), and at times were blatantly hostile:

"I've had somebody shout at me down the corridor – not on the ward but in the corridor – 'We don't want any of your bloody mattresses on the ward any more!' And I've just turned around and had words. You know, it's just a few, it's not everybody but there's just a few who just feel that you're giving them extra workload, but you're not really. In fact you're actually helping them" (CRN4, focus group, March 2004).

CRNs attributed this hostility to ward staff feeling 'threatened' by them and perceiving the CRNs as there to 'check up' on the pressure care that they provided to patients. CRNs indicated that over time they had to develop strategies to survive such hostilities. The focus group participants indicated that they had not anticipated such hostilities towards them because they were all experienced ward-based clinical nurses. They thought that this helped them in their research role and yet other nursing staff seemed to ignore this and treated them as outsiders. Although CRNs initially tried to encourage the ward staff to like them and therefore participate in the study, they later found that they had to change strategies:

"I'm afraid I had to confront, and I couldn't hold my tongue one day, because I walked onto a ward and as I was walking past the desk I heard a nurse comment 'Who's she?' And I said 'You don't know who I am?' And she said 'No!' She didn't make any eye contact with me. And I said 'I've been coming here for 9 months.' And she said 'Have you?' And I said 'It's alright, I'm quite used to being treated like typhoid!' And after that I got a hello every time. I got there because I thought the worm has to turn here, you know. It was like [*names CRN*] was saying about the sales job, you're pleasant and you're nice and you're positive and you're upbeat. And then one day you think, well, no more!" (CRN3, focus group, March 2004).

CRNs emphasised the importance of having someone with whom they could share these reported difficulties. In the NHS trust where there was more than one CRN, they gained support from each other, reporting "excellent teamwork" (CRNb) and going on to "difficult" ward areas in pairs (CRNd). However, in other centres where the CRN worked in isolation, they emphasised the importance of developing relationships with colleagues who they perceived as being in a similar position to them. For these nurses, this was the tissue viability nurse ($n = 3$) or a practice development nurse ($n = 1$):

"… the tissue viability nurse [*name*], has been so supportive – and we've got on so well – that it's made it very easy. And even at times when it's been difficult, and with the difficult characters that I've encountered, she's been somebody that you could speak to confidentially. And invariably she's said 'Oh yes, they're like that with me. Don't worry about it.' And it's nice to know that it's not you, it's them [*ward staff*] really" (CRN6, focus group, March 2004).

Maintaining motivation during the clinical trial

All CRNs reported an interest and enthusiasm for pressure ulcer prevention before the study. However, difficulties experienced during the trial led the CRNs to discuss things that helped to maintain their motivation. The kinds of difficulties

expressed included feelings of isolation and dealing with hostile staff and wards, as already discussed. However, there were additional problems associated with recruiting patients to the study, including the CRN's perceptions that the targets set by the trial team were unrealistic; their feelings that other CRN colleagues, working in other centres, were recruiting more patients; and a feeling that there was competitiveness between centres participating in the study:

> "I just felt sometimes I couldn't account for my day's work. And I knew that I was sort of wasn't skiving. I was doing my best. If I wasn't recruiting patients it was for a good reason. But sometimes to know that X centre had recruited however many patients was a little bit unhelpful to me ..." (CRN6, focus group, March 2004).

Importantly, CRNs also felt that there were fluctuations in recruitment rates and that it was difficult to maintain motivation when their personal expectations of being able to recruit were not being met:

> KS: "What was recruitment like? I mean, what was a good week and what was a bad week?"
>
> CRN9: "It fluctuated."
>
> KS: "Did it go in monthly cycles?"
>
> CRN1: "Yes and over the 3 years it's actually done that each year. August has been usually pretty good and January is, where you would expect it to be good, has been poor. But that was a real stinker for motivation."
>
> (Discussion between KS and two CRNs, focus group, March 2004).

A significant motivator for many CRNs was that they had a previous interest in pressure ulcer prevention. As such, they were keen to improve standards of care for patients and believed that the trial would benefit patient care:

> "I think as individuals we were very enthusiastic about the research because we felt it is an issue on the wards: that pressure ulcer prevention, that it's not up there where it should be." (CRN9, focus group, March 2004).

Other motivating influences included feeling part of a team. CRNs held quarterly meetings to discuss their role and share any difficulties they were experiencing. They reported that these meetings decreased their sense of isolation by increasing their sense of 'belonging' to the trials unit and feeling supported by colleagues and the trial coordinator. It was generally perceived that these meetings facilitated team cohesion, so that when they were experiencing individual difficulties, for example with recruitment rates, they felt able to contact a colleague:

> CRN1: "Well as a group of nurses, we met every 3 months and that was one of the saviours because we all then kept saying 'How do you all feel?'"
>
> CRN4: "And you don't feel so isolated when you know that other people are having a bad time. And it makes you feel better."
>
> CRN8: "You assume, or I assumed, that I was the only one going through this. And then when I came to meetings and you'd be sat there talking about, you know, and all of a sudden …"
>
> CRN9: "You could always ring a colleague and say 'I've got this lady and I'm not recruiting because of this. I'm right aren't I?' Especially if recruitment has been low. 'Well am I missing something?'"
>
> CRN5: "You get to that desperation stage."
>
> CRN9: "And just confirm with your colleagues 'No that was right.' They weren't a problem."
>
> CRN4: "And at [*names trust*] we paired up didn't we? To double-check each other really. To make sure one person wasn't missing. It all ended up the same, that we both agreed to recruit. It always ended up the same, but it was nice to have that other person saying the same thing as you."
>
> (Discussion among CRNs, focus group, March 2004)

The research role experience was generally viewed positively by CRNs and they referred to the longer term influences of the role. Most CRN participants (n = 8) had gone, or were going, back to ward-based clinical nurse roles and emphasised how the research role had helped them to see the wider systems in which they work. They hoped that they could incorporate this into their ward role:

> "You're very insular when you're working on a ward aren't you? You just concentrate on your ward; you don't know anything else that is happening in the trust. And that's what I've found with this job. There's so many things happening out there, that you didn't notice, or look for them in the first place" (CRN4, focus group, March 2004).

However, a CRN already back in practice emphasised difficulties associated with maintaining the wider picture:

> "I found it hard going back and slotting into a team. You had to fight to sort of keep that bigger picture going. And to make sure that you do work in, and around, and what's going on and what's the broader picture. What's happening here and what's happening

there. And not lose it all once you get back into [*ward practice*]" (CRN9, focus group, March 2004).

CRNs stated that their research role had helped them to understand better the research process and gain confidence in using research in practice:

"I think it's an advantage anyway being involved with research as such because I think most nurses I know, this is just me, seem afraid of it and don't know how to implement it in their own practice or challenge it, you know, so I think to actually work somewhere like the pressure ulcer trial, again being nursing research as well again has been very advantageous" (CRN9, focus group: March 2004).

They also felt better able to challenge research because they had developed critical appraisal skills:

"And I certainly have realised that there must have been an awful lot of poor written-up research, which I took it as gospel, you know. When I read these articles, and certainly over the last 5 years, how that has changed. But this experience, this experience in particular, how they actually make sense of what we've collected is beyond me. Throws it into another level really. So I very much more question what I read now. I just sort of took it that it must be right because that's what it said" (CRN1, focus group, March 2004).

Observations of pressure care related specifically to the PRESSURE Trial

CRNs provided observations of pressure care related specifically to the trial. These fell into two areas:

- paperwork associated with the PRESSURE Trial
- mattress use in the PRESSURE Trial.

Paperwork associated with the PRESSURE Trial

CRNs reported that the paperwork for the trial was invariably not adequately completed. This was partly attributed to ward staff perceiving that the trial, and associated paperwork, created an extra workload for ward staff. However, the CRNs suggested that this should not have been the case; the ward nurses should be doing skin assessments anyway as part of care delivery. While the documentation might be different to that usually used in the wards, the CRNs felt that non-completion was strongly related to individual perceptions and attitude:

"Because [*trust*] is so big we were going to wards where there were lots of trained staff and areas that have permanently been with low staff and again it depends on the individual nurse rather than the amount of qualified staff at times, at [*trust*]' because you can have three or four qualified [*nurses*] on and they [*trial paperwork*] still wouldn't get done and it depends on whether they [*ward nurses*] had the interest and that to do it. Because if they were doing that assessment it just meant documenting it in a different way. And again I think we've seen both sides because we've been to such a diverse amount of wards" (CRN5, focus group, March 2004).

Interestingly, one CRN, who had previously worked as an RN on a ward involved in a mattress trial, stated:

"I've had it from both sides. Before I came into the trial, I worked on a ward that's taking part in a mattress trial. It doesn't make any more work, it's seconds to fill the paperwork in. What you're actually assessing, you should be building into your practice" (CRN5, focus group, March 2004).

CRNs also recognised the importance of wider issues as an influence on completion of paperwork. This was because there was variability of paperwork completion both across and within wards. This was, therefore, an issue related not simply to individual staff, but to the ways in which they were influenced by, for example, routines, continuity of staff, other members of their team or leadership:

"And which teams they're working with: who's senior, you know – leadership. You could see which sort of members of the team worked better together, you know, you would walk on a ward and you would know what nurse was in charge" (CRN9, focus group, March 2004).

Another explanation for non-completion of paperwork was the increasing use of, and reliance on, healthcare assistants (HCAs) to provide bedside care because of low numbers of registered nurses in the clinical areas:

CRN6: "I find, from where I'm from at [*trust*], we have got a real problem with staffing levels. I mean most of the wards that I go to are operating with one staff nurse and they are desperate. So what I've found is that a lot of the hands-on care is being done by the carers [*HCAs*] who, I don't mean to sound demeaning, but they haven't got the knowledge base. But what they say is, the nurse relies on what they find because she can't do everything …"

CRN2: "I think that's a very interesting reflection and it would be good to find out whether that has changed over the period of the trial because I would agree with that, that there are less qualified nurses on a shift and I think that is a fundamental change in the last 4 years of nursing and I think that's an excellent point and we've got health carers now,

> we've got health carers who are 'NVQ'd' and skin assessment is part of that. So I do think that is a reflection of nursing."
>
> (Discussion between two CRNs, focus group, March 2004)

At the bedside, CRNs report that HCAs carry out many of the skin assessments, rather than the RNs. RNs were therefore relying on HCAs to inform them of skin assessments so that they could complete paperwork. This created problems for the trial because RNs were supposed to carry out both the assessment and paperwork:

> "I think unfortunately, also some of the wards, the healthcare assistants were doing skin assessments and for the research purposes it has to be qualified nurse doing the skin assessments. And so I suspect that some of it was left because they weren't a qualified nurse …" (CRN3, focus group, March 2004).

CRNs perceived that there was a lack of communication between HCAs and ward nurses which contributed to poor documentation. While this is an issue for the trial, the non-completion of paperwork also has broader implications for general practice. In addition, concerns were raised about classification of pressure ulcers by HCAs who did not classify blistering as a grade 2 pressure ulcer. A CRN reported that there was a lack of availability of consistent pressure ulcer classification criteria within her trust to guide HCAs in their classification of pressure ulcers (CRN6, follow-up, July 2004).

Where paperwork was completed for the trial, CRNs reported some concerns about quality. CRNs revealed that they had some suspicions that ward staff were copying assessments completed by more senior staff:

> "And as research nurses we had suspicions about it – that they were just copying and not actually looking [*at skin*]" (CRN9, focus group, March 2004).

> "You can see it sometimes on the skin assessment charts, they've obviously filled in 5 days in 1 day because it's exactly the same handwriting isn't it? You know, it's the same person and you even suspect that the initials are [*those of*] a health care assistant" (CRN3, focus group, March 2004).

CRNs suggested that there might be a lack of confidence among some ward staff in completing skin assessments and that there may have been assumptions made about the level of RN knowledge to complete assessments for the trial.

Mattress use in the PRESSURE Trial

CRNs expressed that they had two main difficulties in relation to mattress use in the trial. The first was compliance by ward staff with the study protocol. For example, CRNs reported that decisions were sometimes made about mattresses before the CRN had seen the patient:

> "Before I'd had a chance to see them, they'd take a call from A&E and say there's patients waiting to come up and [*ward staff*] put all these [*mattress*] overlays on [*beds*]" (CRN6, focus group, March 2004).

Such actions meant that these patients then had to be excluded from the trial because a decision had already been made about which mattress the patient should be on. CRNs reported having to work constantly with the nurses to increase compliance, with some reporting that they carried out physical work to ensure this compliance, for example moving patients on to the appropriate mattress. CRNs indicated that they did not trust ward staff to comply with the study protocol:

> "If I didn't put the mattresses on the night before they probably wouldn't go on the mattress or they'd get the wrong mattress. The ward staff just were not trustworthy really" (CRN2, focus group, March 2004).

There were also problems associated with taking patients off the mattresses, or 'step-down' care. CRNs reported that the ward staff would leave patients on the mattresses and not reassess and take appropriate actions. Some CRNs reported that patients were left on mattresses until they went home:

> "… they expected you [*CRN*] to make that decision [*taking mattress away*]. When we said that 'We don't want to influence you, how you step people down and things' but they will say, 'They asked to come off it [*mattress*] two days ago or whatever over the weekend but they're still on it.' But they've been told to continue the care as they would normally, so that has arisen at times" (CRN1, focus group, March 2004).

Second, CRNs felt that there was a lack of ward staff understanding of the randomisation process for the trial. Despite the study being a 'randomised' controlled trial, CRNs indicated that some ward staff did not realise that this meant patients were randomly allocated to either a mattress replacement or a mattress overlay:

> "I think I found that they had, a lot of people just didn't get it, that it was a randomised controlled trial and that I wasn't putting them on a Nimbus because I decided that one [*patient*] was far higher risk than that one [*patient*], it was because they either went on

> one or the other and some people just didn't get it. And you just kind of, well, I'm sick of having this conversation [*laughter in group*]" (CRN3, focus group, March 2004).

As such, the CRNs felt that ward staff in some areas were unaware of the implications of the trial. Some ward areas dealt solely with replacements and when CRNs wanted to put patients on to an overlay this would cause anxiety among ward staff because of their routine use of replacements:

> "And there was some areas that really had only ever worked using mattress replacements and then when you were asking them to look at mattress overlays, but that had all been discussed before they consented to be part of the trial, so that became another issue that one had they really understood what they had consented to. But there was quite a difference between the specialties wasn't there about the mattresses" (CRN9, focus group, March 2004).

One CRN, although supported by others in the group, reported that she had concerns about the lack of acceptance by ward staff when a patient refused to participate in the trial:

> "I found it quite surprising also, I had batches, I had five in one day patients refusing to go on air mattresses and it surprised me that the ward staff didn't get it, if they'd said no. I couldn't go and put a mattress on their bed anyway. They cannot compute that people don't have to have everything that we want to do to them in hospital" (CRN3, focus group, March 2004).

As well as observations of pressure care specific to the trial, the CRNs shared their general observations of pressure care in the clinical settings.

General observations of pressure care

The CRNs' general observations of pressure care are considered under three themes:

- standards of pressure care and documentation
- knowledge of ward staff
- lack of appropriate resources.

Standards of pressure care and documentation

CRNs reported variability in pressure area care across clinical settings. In particular, they emphasised that pressure care in elderly care wards was often better than in other specialities, such as orthopaedics. Explanations given for this difference across speciality related to the way in which care was perceived, such that in elderly care wards nurses were viewed as caring for the whole person, whereas in orthopaedics the focus was on the procedure, for example a hip replacement. A further explanation provided by CRNs was based on nurse assumptions about patient groups most at risk, for example older, rather than younger patients, regardless of condition. These are highlighted in the following extract from the focus group discussion:

> CRN1: "I think just different focus from different specialities, I think, plays a significant difference in the care that people receive. Medical elderly had a very different outlook to when I first started going to the orthopaedic areas. They [*orthopaedics*] were very much about the knee, the hip, rather than the whole person. And it did vary, and again it was very patchy I found, the nurses' knowledge."
>
> CRN5: "Do you think it's maybe because the care of the elderly is recognised pressure area care for a long time? Because old people only get pressure areas [*laughter in the group*]."
>
> CRN7: "That's the one thing getting across to staff on some areas could be the idea that only old people get pressure ulcers. I think the care of the elderly, I always find, is reasonably good and I think because the care of the elderly has been well up there in the fact that they're acknowledging. You always see things about elderly people get pressure ulcers and whereas areas that you don't necessarily look after or old people or at risk people, they just see oh you're not old, and so they don't necessarily, it's not yet been recognised that you don't necessarily have to be very old and frail to get a pressure ulcer and I find the care of the elderly as a whole sort of perhaps more."
>
> CRN5: "I think there's a slight difference in ethos that care of the elderly, you do take a very broad sweep through lots of different things: there's pressure area care but also mobility assessment, nutrition, incontinence, etcetera. Whereas orthopaedics they're focusing very much on the procedure. I mean I can think of a gentleman who came in for a knee replacement and he wasn't that old, probably under 60, and the staff were aghast that I wanted to put him in the trial. He had Parkinson disease, he had problems with his medication, he froze post-operatively and he ended up being in bed for 3 days, so he was an ideal candidate. But nobody had connected that he had other problems other than what he was presenting for, which was a knee replacement."
>
> (Discussion among three CRNs, focus group, March 2004)

Criticisms of the narrow focus of the ward nurses were also made in relation to the care provided to patients with a pressure ulcer. CRNs commented on the lack of consideration given to the broader context of care provision when a patient developed a pressure ulcer. For example, CRNs suggested that there was a lack of consideration

given to discomfort experienced by the patient as a result of the ulcer:

> "… you just didn't get people sort of thinking about things and thinking about patients and what else could they do here. Yes, well we're looking at them, and yes they've got a sore, what can we do to alleviate this patient's discomfort?'"(CRN9, focus group, March 2004).

CRNs felt that leadership and role modelling in the clinical area were important influences for the delivery of 'good' pressure care and pressure ulcer prevention. CRNs described areas where there were 'pockets' of good practice:

> "I've certainly seen a lot of good practice as well but it was in little pockets and it depended on sort of, I very much felt it was a leadership thing. A managed point of view. A lot of it or the E grades particularly how they sort of were intertwined within their own team as to how effective they were on each individual ward doing pressure care" (CRN1, focus group, March 2004).

In one centre a CRN expressed concern about sisters/charge nurses not being aware of patients with ulcers. This was particularly because leadership was viewed as so important to standards of pressure care:

> "I think I went with you maybe [*names CRN*] to do one of my assessment things and walked on the ward and saw the sister and said, is it all right with you if we have a look at these patients and go and find some people to talk to and has anybody got any pressures sores of a grade 2 at the moment, because that was one of the ones that we were hoping to see and I can't remember her exact words but basically it came out as, well I haven't looked at everybody's bottom yet! And that was the senior sister on the ward. And we sort of, both of us walked away, and we just went and started seeing patients and both commented on it afterwards" (CRN1, focus group, March 2004).

This lack of awareness was also apparent among some ward staff: ward nurses would report no patients with pressure ulcers, but then CRNs would carry out patient assessments in the wards and find that there were patients with pressure ulcers:

> "Or we've had comments like 'No we have nobody with any pressure damage!' and I think you, well, I have gone onto areas where we've done the initiatory assessments, and that's just not been the case" (CRN7, focus group, March 2004).

CRNs reported that pressure care documentation was also of a variable standard. In some wards they found that documentation was not completed or was inaccurate, for example the document would state 'grade 3 sore on right heel' and yet the CRN would find that the ulcer was on the left heel. CRNs suggested that completion of paperwork was sometimes viewed by ward nurses as a 'tick box' procedure that took them away from bedside care, rather than being viewed as an integral part of patient care:

> "… they've ticked a box to say the patient has been washed, and they've ticked a box to say the patient has been turned, and they've ticked a box to say they've had their dressing changed. And you go, well, you can almost see they've got to Friday and all the dates are ticked, ticked, ticked and that's sometimes what you feel. There just doesn't seem to be that awareness at sometimes writing it down. But you can also understand because a lot of people now say it's a huge amount of paperwork and it detracts from the time that people have got [*refers to time nurses have with patients*]" (CRN1, focus group, March 2004).

CRNs identified that resources played a key part in the provision of pressure care (discussed in a section below). While many CRNs reported on a lack of suitable equipment, particularly a lack of pressure-relieving equipment for chairs, they commented on the subsequent standards of care provided by RNs. For example, rather than leaving patients on appropriate pressure-relieving equipment in bed, ward staff would move a patient out of bed to sit on a chair that was not meeting their pressure care requirements. Sometimes the nurse's decision to move a patient into a chair could be related to their perceived orders from medical colleagues. In some circumstances the CRN would question such decisions and play a role in patient care as a nurse rather than in a research role. This issue was picked up in the previous section on the CRNs' experiences of their role and the importance of professional accountability, above their research role.

CRNs also suggested that there was a lack of time for ward staff to monitor pressure care because of competing demands on their time. For example, CRNs reported that they would often see patients left in the same position for a number of hours:

> "It's this great denial [*by nurses*] though – 'She'd [*patient*] only been there for an hour!' But I knew that she'd been there at 10 o'clock when I went up there, and when I went to recruit a patient at 4 o'clock she was still sitting in the chair. She hadn't moved!" (CRN2, focus group, March 2004).

It was suggested by some CRNs that a way of overcoming some of these difficulties would be to

give patients more responsibility for their own pressure care by providing patient education. Patients could then remind nurses when they think they should be repositioned or to ask for their pressure areas to be checked. However, it was also perceived that this might be difficult for some more vulnerable patients, such as confused older patients:

> CRN9: "I think [*names CRN*] touched on patient education and that was something that we had actually incorporated into our care plans as patient education for pressure relief."
>
> CRN1: " And them taking some responsibility of …"
>
> CRN9: "But it's also getting at the nurses through the patients as well, to say put them back to bed."
>
> CRN1: "Yes you can be quite clever can't you – some manipulation, negotiation."
>
> CRN9: "'Yes, I've checked my pressure areas today!'" [patient voice]
>
> CRN1: "The only difficulty then is when patients are confused, the most vulnerable are the medical elderly ..."
>
> (Discussion between two CRNs, focus group, March 2004)

There was also criticism of management of pressure ulcers. CRNs felt that ward staff did not always appreciate that putting a patient on a pressure-relieving mattress was not the entire care required for a patient; there should also be attention to dressings and repositioning. CRNs reported that they perceived a lack of attention to pressure ulcer prevention once a patient was on a mattress:

> CRN8: "Do you find as well with patients on a mattress, they [*ward staff*] accept that as fully, well, that'll do for them?"
>
> CRN6: "That they don't need to do anything else."
>
> (Discussion between two CRNs, focus group, March 2004)

During the focus group there was a lack of discussion of dressings for pressure ulcers. At follow-up interviews, CRNs were asked specifically about dressings. This revealed diversity across the two centres included. One CRN reported that a pressure ulcer of grade 2 was not routinely dressed and "not seen as a problem by nurses" (CRN4, follow-up, July 2004). However, if the ulcer was deeper then this would get 'more of a reaction' from the nurses and they would commence dressings. CRN6 described a more standardised approach to the dressing of pressure ulcers. Advice regarding dressings was on the hospital intranet and updated by the tissue viability nurses. CRN6 reported that specific advice was available for the dressing of grade 2 and grade 3 ulcers, an ulcer with exudate and infected ulcers. However, CRN6 expressed concerns that ward nurses were becoming over-reliant on tissue viability nurses, because they would contact the specialist about all grades of pressure ulcers, including reddening of the skin (CRN6, follow-up, July 2004).

Knowledge of pressure care

There was discussion among CRNs about the level of pressure ulcer knowledge among ward nurses participating in the trial. Some CRNs suggested that there had been a decline in the priority attached to pressure ulcer prevention in some of the wards and that the knowledge base for care provision was not always in place:

> "I can see sort of a difference there – it really sort of opened my eyes and I found it scary and professionally concerning that the knowledge base just didn't really seem to be there" (CRN9, focus group, March 2004).

These observations were being compared to standards of care observed by CRNs in their wards before taking on the role of CRN, and so there may be some hindsight bias in these statements. Indeed, some CRNs disputed this observation of decreasing knowledge levels and suggested that care might not always be optimal because of resource issues, rather than related to a lack of knowledge. For example, WNs might be aware that a patient required a pressure-relieving cushion on their chair, but the ward budget did not cover this expense and so the equipment was not made available because of a lack of financial resources. However, all CRNs felt that there was a lack of knowledge about pressure-relieving equipment. Take the following example, where CRNs discussed the use of mattresses and problem-solving when they alarm:

> CRN2: "I've actually stopped somebody from changing a mattress and it was simply that the CPR stopper wasn't in and yet they reckoned this mattress was faulty and they didn't think to …"
>
> CRN9: "And they can listen to them alarming. I don't know how they can cope with the sound!"
>
> CRN2: "Or else they switch the mattress off and plug it back in and it gives them 2 minutes of peace before it alarms again!" [*Laughter in the group*]
>
> (Discussion among three CRNs, focus group, March 2004)

There was some general concern among participants of the focus group about the categorisation of patients susceptible to pressure ulcers and the prescription of care based on these categorisations:

> "But it seemed to me that they still had an experiential idea of what a patient should be put on. If someone met a certain criteria for them, in their experience you know, very old, very frail, had been lying for 6 hours and hypothermic – put them on an MR [*mattress replacement*]. But if they were relatively well cared for, they would put them on an overlay. And sometimes it didn't seem a rhyme or reason for it" (CRN9, focus group, March 2004).

> "I'm sure that they (ward staff) pigeon-holed people, if they come in for this or they've arrived with that then they need to go onto that, I don't know, that was something that quite surprised me in some way" (CRN8, focus group, March 2004).

This has been alluded to in the earlier example highlighting the lack of risk attached to orthopaedic patients compared with elderly patients, "only old people get pressure ulcers" (CRN5).

Interestingly, the CRNs went on to discuss the notion of individualised care and suggested that this categorisation of patients was widespread and meant that patients received prescriptive rather than individualised care:

> CRN7: "It comes back to that sort of prescriptive nature of the patient, isn't it? You come in for this procedure, you are this age, you will be in bed for this long, you will have that mattress, you will take these medicines and on that date you will go home! And it's like prescribed."
>
> CRN1: "And everybody writes down 'Patient received individualised care'!"
>
> CRN3: "Yes." [*Agreement from others in group*]
>
> (Discussion among three CRNs, focus group, March 2004)

These comments reflect the CRNs' scepticism about levels of knowledge among RNs and the provision of care best suited to patient requirements.

Resource availability

Mattress use was discussed at length by CRNs in the focus group. In particular, this related to the 'territorial' use of mattresses and the issue of lack of resources.

CRNs explained that there was an unequal distribution of mattresses both across and within centres participating in the trial, such that one ward within a centre had a plentiful supply of mattresses and the ward next door did not, but there was no sharing of equipment:

> "I think the thing that came out as well, was that some areas were flush with mattresses and some weren't. And again that was where the territorial came in, they wouldn't allow the ward next door to have them. They would rather have them lying on the bathroom floor" (CRN8, focus group, March 2004).

Some centres had their own supply of purchased mattresses, yet others used rental supplies. The general feeling of CRNs was that hiring of mattresses was the better option because supply could then meet demand and the equipment was looked after.

CRNs were keen to share their observations of equipment abandoned in store cupboards because it had not been looked after appropriately. The following discussion among CRNs raises some important issues in relation to the use of mattresses and the appropriate use of financial resources in the NHS:

> CRN5: "There's no responsibility for arranging for mattresses to be serviced – it's nobody's job, you know. The number of pieces of equipment just stuck in cupboards that could be used, for the want of being serviced."
>
> CRN3: "And finding mattresses that are disgustingly soiled and nobody will pay to have them decontaminated! So there's just stinking mattresses in carrier bags here there and everyway because nobody has a budget to maintain these thousands of pounds worth of equipment that they've bought. They don't seem to sort of think ahead that this stuff might break and that they might need to repair it with something."
>
> CRN4: "I think that's maybe fortunate [*in that*] that we have a contract and everything is decontaminated."
>
> CRN1: "They do at [*trust*]."
>
> CRN6: "I think ours was very patchy. Some wards deal with that very well and other wards, I don't know how you found that [*names CRN*] recently, but I think some wards do it very well."
>
> CRN5: "I think probably patients who we end up renting a mattress for in a sense get a better deal because you know that the mattress has been serviced, it has been decontaminated between use."
>
> CRN1: "Because at [*trust*] we do both. We rent if we haven't enough or we have our own supply so we actually have a mixture of both systems."
>
> CRN3: "And some of them [*patients*] are on the bed and they smell! It's so embarrassing and you just

think, shall I take it off? Can I say well this smells and I'm going to take it off? Or can I get round of not having to explain why it smells? It's very embarrassing. And somebody has taken that off a bed and slung it somewhere without thinking that it was suitable for the next patient."

CRN4: "I don't think I've ever come across a smelly one."

CRN3: "There are hoards of them! But all of them are in-house. Nothing is rented and nobody pays for anything to be cleaned."

CRN4: "And yet you had that super influx, what 18 months, two years ago, of all those lovely new mattresses, didn't you? And nurses had cried out for equipment and then nobody seems to take responsibility for looking after them!"

CRN7: "There isn't a budget. If there's something, say I report a mattress because the little CPR thing has gone, has been lost, there isn't any money available to buy a new thing to stick it in the hole. So it [*mattress*] gets shoved in a cupboard and so they don't seem to – when they buy, they invest thousands in equipment but not in maintaining the equipment. It just seems diabolical!"

CRN4: "It's actually the cost of an operation or whatever!" [*Agreement in group*]

CRN3: "And I mean there's been a couple of mattresses that patients have gone berserk and ruined – they've ripped the covers and such like. And there's about four or five, probably about five, Nimbus's sat in a cupboard because there isn't any money to buy top and bottom covers. And that's literally all that's the matter with them. They just need top and bottom covers and that's thousands! You could probably buy a small house with how much money is sat in a cupboard!"

CRN7: "It is budgetary because if you think how much a trust maybe gets sued because somebody's relative has died because of a sore or has developed a sore and has been in hospital for months. And there doesn't seem to be that link. And it is budgetary, it's here and now isn't it? In [*Centre X*], how many millions have we to save by the end of this month? But it's that budgetary link that we've got to think about now and yet the trust pays out thousands for people being in hospital for months or even from somebody dying because the family sue. There doesn't seem to be that link, they don't seem to have made that connection." [*Nodding from other participants*]

CRN3: "And none of that equipment belongs to anybody. It's shared between the hospital. So if a patient on a ward contaminates a mattress they don't see why they should have to pay £100.00 to have it decontaminated because it's not their mattress. So [*names CRN*] and I were sat with mattresses full of wee for months, while I've been badgering different people to get the damn things cleaned. And in the end you go to the top and write a very rude email that you wouldn't have probably written if it had been sorted out earlier! It's just appalling and there's no where to put these mattresses full of wee either!"

(Discussion among CRNs, focus group, March 2004).

This dialogue presents the following issues related to resource availability, including wasted ward equipment resources, a lack of ownership among ward staff for ward equipment resources, infection risks, lack of financial planning for the upkeep of ward equipment, the benefits of using equipment from a contractor and the problems associated with equipment being allocated by ward.

Limitations of the substudy

The findings present the views and observations of a small group of CRNs working on the PRESSURE Trial. Therefore, there are limitations associated with the generalisation of these findings to other settings. However, the findings do provide useful data to help to explore, and possibly explain, some of the findings from the PRESSURE Trial by providing contextual detail for the settings under study.

The focus group method is criticised because of the possibility of group conformity.[72] The CRNs knew each other before the focus group meeting and so there was a possibility that this would occur during the discussion. However, within the group discussion, all of the participants contributed and there were examples where they challenged or disagreed with each other. Based on the transcriptions, group conformity did not appear to be an issue in this particular focus group. The findings are limited, however, because only one focus group session was carried out.

Analysis of the focus group raised further questions and identified gaps in the discussion, in particular, the opportunity for CRNs to reflect on their positive experiences in their role (overwhelmingly the focus was on negative experiences) and to discuss dressings applied to pressure ulcers in the different centres. Follow-up interviews addressed these gaps, but are limited by the fact that it was only possible to interview two nurses (out of five contacted) who had attended the focus group.

Summary

The focus group provides data highlighting the experiences of CRNs participating in the

PRESSURE Trial and their observations of pressure care specific to the trial and of care more generally. The main themes presented in the data are:

- experiences of CRNs:
  - difficulties in adapting from a ward-based clinical to a clinical research role
  - challenges in setting up and running the clinical trial
  - maintaining motivation during the clinical trial
- observations of pressure care related specifically to the trial:
  - inadequate or incomplete completion of paperwork associated with trial
  - inappropriate mattress use in the trial
- general observations of pressure care:
  - variable standards of pressure care and documentation
  - gaps in RN knowledge of pressure care
  - limited pressure care resources.

Chapter 7
Discussion

This RCT compared alternating pressure mattress replacements with alternating pressure mattress overlays for the prevention of pressure ulcers in at-risk hospital patients. Both interventions are in widespread use throughout the NHS and have the same mode of action, although there are large differences in purchase price (approximately £1000 for an overlay and £4000 for a replacement). This is the first head-to-head comparison of these technologies and the largest RCT in pressure ulcer prevention that the researchers were able to identify.

Outcomes

Proportion of patients developing new pressure ulcers

There was no difference between overlays and mattress replacements in the primary outcome, namely the proportion of patients who developed a new pressure ulcer of grade 2 or above at any anatomical site. During the trial, 10.7% of patients allocated to the overlays and 10.3% of those allocated to the replacement mattress developed pressure ulcers. The point estimate for the difference in proportions of patients developing a new ulcer (0.4%, 95% CI –2.3 to 3.1%) means that it is unlikely that the true difference could exceed the 2.3% lower incidence to a 3.1% higher incidence for overlay patients. Logistic regression to adjust for prespecified covariates and minimisation factors confirmed the conclusions from the unadjusted analysis, namely that there was no difference in the proportions of patients developing new pressure ulcers between the two surfaces.

Time to new pressure ulcer development and proportions of patients developing ulcers within 30 days

It was important to determine whether either surface delayed the development of new pressure ulcers, particularly since the probability of developing an ulcer reduces over time. Unadjusted comparisons found no statistically significant difference in time to new ulceration, or in the proportions of patients developing a new ulcer within 30 days (10% of patients on overlays and 9.3% of patients on mattress replacements, $p = 0.58$). The 30-day time-point was chosen since most patients develop pressure ulcers early in their hospital stay and it was also considered feasible to follow a large proportion of patients up to this point.

Cost-effectiveness analysis

In this study costs were defined as mattress costs and hospital costs (the latter as the product of length of stay and hospital costs per day). No further costs associated with pressure ulcer treatment were estimated, based on the observation that grade 2 ulcers did not usually receive a wound dressing. The health benefits associated with the interventions were captured as pressure ulcer-free days. This approach was chosen rather than the more usual method of trying to capture a patient's utility through changes in quality of life because it was felt that trying to collect such data from very ill patients was impractical and their concurrent illness would dominate any quality of life measurement. The assumption that patients would have remained on the trial mattresses for the duration of their stay, although unlikely to be true, means that the estimates of the difference in cost are conservative. In reality, because the mattress replacement was associated with a longer ulcer-free period patients in this arm were likely to be moved to cheaper alternatives more quickly; thus, the cost in this arm has been overestimated.

The mean length of hospital stay (unadjusted) of patients in the replacement group was 1 day shorter than that of overlay patients (19 versus 20 days). The skewed nature of length of stay data (few patients have extended lengths of stay) means that conventional, unadjusted estimates may be prone to chance bias. A GLM was used to adjust the estimates of mean duration of hospital stay and total costs and this indicated a 0.4-day reduction in length of stay in favour of mattress replacements.

The mattress replacement was economically dominant since it was associated with lower overall costs (£74.50 per patient on average, mainly due to reduced length of stay) and greater benefits (a delay in time to ulceration of 10.64 days on

average). Consequently, an incremental analysis of the costs and benefits associated with the overlay and mattress replacement was not necessary. While these differences in costs and benefits are not statistically significant at the 5% level, an analysis of the uncertainty associated with the decision to use replacements instead of overlays indicated that there is a 64% probability that mattress replacements are cost-saving (*Figure 9*). It has been argued that, in the context of healthcare decision-making, traditional rules of inference are irrelevant since decision-makers cannot delay their decisions until sufficient research evidence accrues,[73,74] and instead healthcare decisions should be based on mean net benefit irrespective of whether traditional levels of statistical significance are reached. This approach is in line with guidance issued by the UK National Institute for Health and Clinical Excellence (NICE).[40] Therefore, the information provided by this trial suggests that replacement mattresses have the highest probability of being cost-saving compared with overlays.

Adverse events

There were only nine adverse events related to the use of either mattresses or overlays (seven on replacement and two on overlay). Adverse events such as falls were often not observed by ward staff and consequently there was difficulty in attributing incidents to the use of a trial intervention. The rules for assigning causality in this study mean that it is more likely for treatment-unrelated events to have been classified as treatment related than the reverse. Falls and problems with bed-rails were the most common type of event. It must be emphasised that falls in older hospital patients are extremely common (there were 149 falls in 316 control group participants in a recent trial of a fall prevention programme for elderly hospital patients).[75]

Problems with bed-rails may arise because the use of replacements and overlays raises the height of the support surface relative to the adjacent bed rail, potentially increasing the possibility of patients falling out of bed over the top of the rail. The possibility is of particular concern for overlays, since they are placed on top of standard mattresses, increasing the total height of the support surface to a greater extent. Although this study did not detect any difference in the numbers of adverse events between the surfaces, because there were so few adverse events (there were two bed-rail-related incidents involving a single patient on an overlay and one for mattress replacements), staff should be always be extremely safety conscious when bed-rails are used in any context. It must also be emphasised that no conclusions whatsoever can be drawn about the relative risks of adverse events occurring on alternating pressure surfaces compared with other mattresses and overlays in use in the NHS.

Patient acceptability

Patient acceptability was a secondary outcome in this trial and was captured by patient requests for a mattress change owing to dissatisfaction with the mattress or overlay. More patients allocated overlays requested mattress changes owing to dissatisfaction (23.3%) than mattress replacement patients (18.9%, $p = 0.02$). In addition, patients provided with an overlay mattress reported more problems with aspects of mattress comfort, motion, movement in bed, getting into/out of bed, temperature and other general features than patients provided with a replacement mattress at baseline. Overall, 27.0% of patients who completed the comfort questionnaire reported that comfort was unacceptable and it is noteworthy that a large proportion of patients (63.8%) responded negatively about one or more functional aspects of the alternating pressure device, with more than one-third of patients reporting difficulties associated with movement in bed and getting into/out of bed. These difficulties seem to arise because the soft edges and unstable nature of the mattress/overlay make it difficult for patients to balance or get any purchase when trying to brace or get up (a particular problem in an elderly population who are at risk of falling and often have a fear of falling). The maintenance of mobility is extremely important in older hospital inpatients and factors that militate against this are of concern. Manufacturers may need to consider whether there are amendments to design that could be made to reduce these problems, particularly with regard to reducing the softness and instability of the surface edges.

Staff acceptability and knowledge

There was concern at trial outset that ward-based nursing staff, who retained full responsibility for patient care during the trial, would be unwilling to allocate overlays to patients judged by them to be at 'very high risk'. This was evidenced during the trial through clinical decisions at randomisation and ward-led mattress changes. Ward-based nursing staff sometimes intervened after mattress allocation at randomisation (ten times for overlay patients and twice for patients allocated mattress replacements) and during the follow-up period (29 times for overlays and 22 times for replacements) for clinical reasons. In addition,

patients allocated a replacement were more likely to have a ward-led mattress change in order to give the mattress to another 'more needy' patient [21 times (14.8%) for patients on replacements compared with 10 (6.7%) on overlays]. Although these mattress changes introduce bias, the number of such changes was small and the results of both the ITT and PP analysis were similar, suggesting that the mattress changes do not impact upon the main trial conclusion.

More overlay mattresses (207 problems reported for 131 mattresses) were reported to have a technical problem compared with 172 problems for 92 replacement mattresses; however, staff may have been more likely to report a fault for a surface in which they had less belief. There were particular problems with the resuscitation pull and settings for overlay mattresses, frequent alarm triggering for the replacement mattresses, and low pressure for both overlays and replacements. Staff knowledge was not directly assessed, but reports of technical problems with both mattress types illustrate the extent of misuse. On 75 occasions the mattresses were not connected to the power supply or not turned on, and on 30 occasions the mattresses were found in static 'transport' mode. The often poor care and maintenance of mattresses was raised by the CRNs in their focus group interview, and hospital managers must ensure that equipment is adequately cleaned and maintained, and that clinical staff know how to use the equipment.

Pressure ulcer healing

Only 113 patients entered the trial with an existing grade 2 pressure ulcer (and the protocol excluded recruitment of patients with ulcers of greater severity as some clinical staff were reluctant to randomise to mattress overlays for these patients). Healing rates for ulcers that developed during the trial were not measured. Consequently, this trial is underpowered to detect important differences in healing rates; however, the healing data for both surfaces were similar, with 33.9% healing on the overlay and 35.2% healing on the replacement. The Kaplan–Meier estimate of the median time to healing for both groups was the same (20 days), but confirmatory research is needed.

Risk factors for pressure ulcer formation

Several factors emerged from the logistic regression model as significantly predictive of future pressure ulceration in patients admitted to hospital. Predictive factors were acute versus elective admission (OR 3.65, 95% CI 2.27 to 5.85), a baseline chronic wound versus no wound (OR 2.96, 95% CI 1.73 to 5.08), baseline skin trauma (OR 1.67 95% CI 0.999 to 2.80) and non-blanching erythema versus those without (OR 1.95, 95% CI 1.31 to 2.91). Other significant factors included older age (OR 1.02, 95% CI 1.002 to 1.04), lower haemoglobin (OR 0.89, 95% CI 0.82 to 0.97) and diabetes (OR 1.61, 95% CI 1.007 to 2.56). Previous studies have identified non-blanching erythema;[16,18] and increasing age[14,15] as predictive in hospital inpatients, but diabetes has only previously been identified in elderly nursing home patients[76,77] and anaemia in intensive care patients.[20] The notion that acutely ill patients are more at risk than elective patients is unsurprising, since patients deemed to be fit for elective surgery will be more physically robust. Pressure ulceration is likely to be largely a consequence of complex interactions between factors intrinsic to the individual that influence their ability to tolerate pressure (e.g. haemoglobin) and the magnitude and duration of the applied pressure. The role that diabetes may play in the development of pressure ulcers is unclear. Diabetic foot ulcers are themselves usually a version of pressure damage, due mainly to a combination of neuropathy, excessive plantar pressure and trauma in the presence of vascular disease and disorders of skin metabolism.[78] In total, 16.3% (31/190) of participants with diabetes developed a new pressure ulcer in the trial, of whom 3.2% (6/190) developed a heel ulcer. This contrasts with the 9.9% (176/1770) of people without diabetes who developed a pressure ulcer, of whom 1.5% (26/1770) developed a heel ulcer. Whether people with diabetes are more susceptible to pressure ulcers of the heel is something that deserves more scrutiny in future research.

Existing skin wounds are probably predictive merely because they signal the vulnerability of that patient's skin to trauma and pressure.

Potential explanations of the findings

The conclusion that the replacement mattress is economically dominant may initially seem counterintuitive. The replacement mattress has a higher purchase cost and no statistically significant effect on the proportion of patients developing an ulcer, the time to ulceration, the severity of ulcers developed or length of stay. However, the purchase cost of replacement mattresses is low when typical mattress lifespan is taken into

account, and the difference in costs between overlays and replacements becomes extremely small over their lifespan. The average mattress cost per day (based on a 2-year lifespan) was calculated at £1.40 for an overlay and £5.70 for a replacement. Any difference in cost here is small in the context of the cost per day of inpatient stay (between £165 and £385 depending on speciality) which was, on average, 0.40 of a day less for mattress replacement patients, translating to an average reduction in costs of £74.50 per patient in favour of the mattress replacement. The health benefit associated with the interventions was measured as the difference in mean time to develop a pressure ulcer, and also favoured the mattress replacement (by 10.64 days). This delay in ulceration associated with the mattress replacement is crucial, since the longer a patient avoids ulceration the less likely they are to go on to develop one; a delay in ulceration buys the patient time to recover sufficiently from their acute episode so that their risk of ulceration recedes. It may be argued that although time to ulceration was a secondary end-point in this trial, it should be considered as a primary end-point in future studies since it is more informative, both economically and for patients.

The 'clinical' analysis presents the estimated median time to pressure ulcer development and found no statistically significant difference between the groups, while the economic analysis used the mean time to pressure ulcer development. The difference in approaches is explained by the need for economic evaluation to inform purchasing decisions and resource allocation. For such decisions the mean is more informative than the median, as multiplying the mean by the envisaged throughput of patients produces the total bed-days that would be used, whereas this is not the case with the median for skewed data.

Total cost is a function of hospital length of stay, which itself is mainly a function of overall health status. Therefore, patients with higher morbidity are more at risk of both pressure ulceration[14] and a longer length of stay. The development of a pressure ulcer is a consequence of the morbidity and can be delayed or averted by nursing care; however, the relationship between these two factors is not understood. It is likely that provision of a support surface will prevent ulcers in a proportion of patients, and will merely delay the appearance of an ulcer in others. If the appearance of an ulcer is a proxy for acuity, and more acutely ill patients consume more healthcare resources, then any delay in pressure ulceration reduces the consumption of healthcare resources. The longer length of stay in patients with pressure ulcers is probably a consequence of co-morbidities rather than the presence of a pressure ulcer. When the researchers tested to see whether the different mattresses had a differential effect on length of stay depending on the presence of a pressure ulcer no effect was found; overall length of stay for patients who developed an ulcer on either mattress was similar.

Potential litigation costs were not taken into account in the economic evaluation as these are hard to quantify and depend on a successful claim for negligence. However, the NHS Litigation Authority (http://www.nhsla.com/home.htm) was contacted to obtain information regarding the frequency and size of claims for pressure damage. It was found that 56 claims were registered between April 2002 and April 2004 and these include four instances where the patient died. The average cost of a claim was reported as £37,295, but ranged up to £375,000. Inadequate nursing care, lack of assistance and care, and failure or delay in diagnosis were frequently cited as causal and therefore the CRNs' observations in this trial regarding frequent poor quality of care should act as a warning throughout the NHS. Trial staff often observed poor documentation of pressure area status in the NHS patient record (including lack of documentation of the presence of pressure ulcers), and ward nurse pressure area assessments could not be used in the analysis as planned because of concerns regarding the reliability of recorded skin assessments. The focus group interview with trial CRNs was designed in part to capture their perceptions of the quality of pressure area care generally, since they had been ideally placed, as informal 'participant observers'. Clearly, this interview was post hoc and CRNs were not asked to document their observations contemporaneously. Nevertheless, the authors think the reports ring true and were in part supported by trial data (on documentation, and comments from non-trial patients in the interview study that their reports of sore skin were ignored). The reports that pressure area care is often given low priority outside care of the elderly wards, that senior staff were often unaware that patients had pressure damage, that the dangers of leaving at-risk patients sitting in chairs for long periods were often not recognised, and that pressure ulcers of grade 2 (i.e. broken skin) were often not dressed are worth emphasising. Not surprisingly perhaps, there was a perception that good clinical leadership from senior ward nurses had a large impact on the

quality of care; an observation supported by previous research.[79]

As outlined in Chapter 1, no cost–utility analysis was planned in this study, as the measurement of utility would be completely confounded by co-morbidities. The substudy, however, has highlighted very real impacts on quality of life associated with pressure ulceration. This substudy makes a real contribution to what little was previously known about the effects of pressure ulcers on the patients who experience them. Clearly, the impact of pressure ulcers varies depending on context, but the patients' own voices indicate the physical, emotional, mental and social impact, sometimes involving lengthy hospital stays and much pain and discomfort. Patients' accounts also highlighted that the development of a pressure ulcer could be pivotal in the trajectory from illness to recovery, by preventing full recovery or causing varied impacts on their quality of life.

Comparison with similar studies

This is the first head-to-head comparison of alternating pressure overlays with alternating mattress replacements; therefore the authors can only look to see whether the risk of pressure ulcer development associated with alternating pressure was similar to that observed in previous studies, in similar populations. In the PRESSURE Trial, 10% of participants developed an ulcer within 30 days of randomisation. A recently updated systematic review[33] identified 12 RCTs (14 treatment arms) in which at least one arm received alternating pressure (a mattress replacement in each case). The risk of ulceration on alternating pressure across these trials ranged between 0[80,81] and 54%.[82] The study by Conine and colleagues[82] studied patients quite dissimilar from those in this trial, namely, people with neurological disease aged between 18 and 55 years. The studies most similar to this one, evaluating some form of alternating pressure mattress in (mainly) older hospital patients, reported pressure ulcer risk on alternating pressure as follows: Hampton 0,[80] Taylor 0 and 9%,[81] Price 2%,[83] Gebhardt 16%,[84] Exton-Smith 16% and 39%[85] and Stapleton 34%.[86] Clearly, the risk of ulceration reported in the PRESSURE Trial (10%) is consistent with these wide-ranging figures.

Strengths of the study

The PRESSURE Trial has several strengths worth emphasising. First, with a sample size of 1971 participants it is adequately powered to detect a clinically important effect on pressure ulcer risk even at fairly low rates of ulcer incidence (although it had been planned to recruit 2100 patients this shortfall has minimal impact on statistical power). The sample sizes in previous trials of beds and mattresses for pressure ulcer prevention have ranged between 12 and 1166 (median 80).[33] Second, rather than merely reporting proportions of patients developing a pressure ulcer within an arbitrary follow-up period, time to pressure ulceration was reported; this is arguably the primary outcome of choice for future studies as it is the more meaningful measure for the economic evaluation and possibly also from a clinical and patient perspective. Third, the trial was conducted to high standards,[38] including remote, concealed randomisation and ITT analysis, and with assiduous attention to data quality and reporting. Aspects of care such as mattress changes and adverse events were carefully documented; these parameters receive almost no attention in existing reports of pressure-relieving device trials and yet this experience indicates that they are inevitable. Fourth, and importantly, this trial was pragmatic in nature and the findings are highly likely to be representative of what would happen in usual clinical practice. Finally, the authors believe that the two substudies add a unique perspective. The quality of life study has given a voice to the patient experience and described the wide-ranging impact of pressure ulcers on all aspects of life and the healthcare experience. The interviews with the CRNs both captured the highs and lows of being a research nurse in an area sometimes accorded little clinical importance, and gave some insight into some shortcomings in the standards of patient care.

Study limitations

Probably the main limitation of the trial was the lack of blinded outcome assessment. The researchers identified at an early stage of planning the trial that this would be impossible to achieve since it is not possible to disguise or mask the mattresses and it would be unethical frequently to move seriously ill, elderly patients onto a standard surface for their skin to be assessed. Steps were taken to minimise the potential for bias this allows, by collecting independent skin assessments conducted by both the ward staff and the CRNs. As discussed, the researchers became increasingly concerned about the standard of ward staff data; not because of concern about bias so much as accuracy. Similarly, clinical ward staff were not

blinded to which mattress patients had been allocated and clinical decision-making (regarding co-interventions such as 'turning' or the decision to change a mattress) may have been influenced by knowledge of the allocated treatment. There is no evidence that this was the case, however, and it is reassuring that the mattress changes do not appear to have impacted on the primary end-point. The frequent mattress changes are in a sense both a strength and a weakness: while they represent real-life mattress use, they provide generalisable data; however, it is extremely difficult to attribute end-points to the randomised surface since the patient may only have been exposed to that surface for a short period and well before the end-point was reached.

Furthermore, while data were collected for up to 60 days of a hospital episode, relatively few data were obtained about what happened to the patient between the 60-day time-point and hospital discharge. There is also little information regarding co-interventions, such as wound dressings and nursing care (e.g. turning), because these data would have been extremely resource intensive to collect and would have required more personnel.

The study, as designed, enabled the cost of preventing pressure ulcers to be calculated, but the savings accrued from pressure ulcers averted could not be calculated because it is not known how much pressure ulcers cost. This means that the estimate of cost savings associated with mattress replacements is likely to be highly conservative. There is no robust estimate of the costs of pressure ulcers in the literature and such a costing study would need to be large and conducted in several centres to ensure generalisability, and would require careful observation of nursing care. It was clearly not possible to undertake such a costing study within this trial.

Generalisability

The population from which the trial participants came is typical of people at risk of pressure ulceration in UK hospitals. Patients were eligible to be recruited from care of the elderly and medical wards, orthopaedics and vascular surgery if they were aged 55 years or older and were immobile or had very limited mobility (or were expected to after surgery) and/or had a pre-existing pressure ulcer of grade 2 or lower. The reality of recruitment patterns meant that 79% of patients actually recruited were from orthopaedic wards, with only 17% from care of the elderly wards and approximately 4% from vascular surgery. The eligibility criterion of expected length of stay of 7 days or more reflected the typical length of stay for people undergoing surgery for fractured neck of femur, hip replacement and knee replacement when the trial began, although length of stay for these procedures is probably now lower. The authors believe, therefore, that these results are generalisable to older people undergoing these procedures today. How far these trial results can be applied to care of people over 55 years with severely impaired mobility irrespective of their diagnosis or to people in different care settings (e.g. nursing homes) is open to debate and depends on the extent to which patients with different diagnoses are likely to share the same risk factor profile. A further factor that limits generalisability was that 2286 potentially eligible participants could not be recruited because they were unable to give informed consent (too ill, unconscious or confused) and did not have a relative available. However, these results are likely to be applicable to the care of older people who are completely immobile or have severely limited mobility in orthopaedics and care of the elderly type settings in acute hospitals. Patients admitted for vascular surgery have some degree of impaired circulation and hence impaired tissue perfusion, and there were only 74 of them recruited to the PRESSURE Trial. However, the results do not suggest that vascular patients were at higher risk than the other groups (risk of ulceration was 0.12 compared with 0.09 for orthopaedic patients, and 0.17 for care of the elderly patients), so there is no obvious reason why the results would be expected to be different for them (many of the patients classified as orthopaedic or care of the elderly will also have had vascular disease, but it was not their primary diagnosis for this admission). The results apply to both acutely admitted and elective surgery patients. However, the results of this study are unlikely to be generalisable to extremely high-risk patient groups such as those with neurological disease or injury (e.g. people with spinal cord injuries) or to other groups of younger, physically disabled people with severely limited mobility.

The researchers are confident that the results are applicable in different hospitals as patients were recruited from 11 different hospitals, including large teaching hospitals, smaller district general hospitals and small hospitals with a primarily rehabilitation function. The participating hospitals were situated in big cities and small towns, ensuring broad generalisability.

The approach of having broad trial specifications for eligible trial mattresses and overlays enabled the researchers to allow centres to use their usual overlays and mattresses within the trial, that is, those with which staff were familiar. Variation was kept to a minimum within each centre by requiring that a hospital received the majority of mattresses/overlays from one manufacturer (via either rental or purchase). This means that the results of the trial are broadly applicable to any mattresses and overlays that fit the specifications outlined in *Table 4*.

Clinical implications

While the clinical findings indicate that a similar proportion of patients will develop a pressure ulcer within 60 days, whether nursed on an alternating pressure overlay or mattress replacement, the results of the economic analysis indicate that alternating pressure mattress replacements have a higher probability of being cost-saving (64%). Mattress replacements were associated with lower average costs (from reduced length of stay) and greater health benefits (more pressure ulcer-free days as a consequence of delayed ulceration) and were better received by patients. The authors believe these results support current practice, with more mattress replacements currently used than overlays.

The results suggest that when renewing alternating pressure surfaces or ordering equipment within a rental contract, mattress replacements should be specified; however, overlays are acceptable if no replacement mattress is available. Similarly, patient preferences can be supported, without any great increase in risk, if individual patients request an overlay rather than a replacement mattress.

The PRESSURE Trial findings are in line with recommendations made in the recent RCN *Clinical practice guidelines for pressure ulcer risk assessment and prevention*,[31] which state:

> Recommendation 5.3 Patients at very high risk of developing pressure ulcers should be placed on alternating pressure mattresses or other high-tech pressure redistributing systems (Strength of the Evidence II).

Clinical nurses and their managers should ensure that the pressure area care they provide is of the highest possible quality and in line with current clinical practice guidelines, particularly in the areas of avoiding prolonged chair-sitting for at-risk patients, the need for accurate and regular documentation of skin status and the use of wound dressings for open wounds. This study has provided evidence that approaches to pressure area care (e.g. whether patients are listened to by staff when they report discomfort or pain) and the development of pressure ulcers often have a hidden emotional, mental and social impact as well as a physical one, and staff should take this very seriously.

Research implications

This trial has demonstrated that adequately powered, rigorous randomised trials in pressure ulcer prevention are possible, although challenging. Many important clinical uncertainties in the field of pressure ulcer prevention have not yet been addressed by researchers and the research agenda is relatively untouched. The obvious research question arising directly from this trial is whether alternating pressure mattress replacements confer any advantage over high-specification foam mattresses in patients at moderate to high risk. It may not be possible to answer this question in the UK, where alternating pressure surfaces have become the standard for at-risk patients.

Future trials in pressure ulcer prevention should measure time to ulceration as the primary end-point, since this is more informative economically and possibly also from a patient and clinical perspective.

There is a need for an accurate costing study to understand better how much pressure ulcers cost health and social services in the UK. This type of study would include observation of care actually received by patients with pressure ulceration, including wound management. Such an understanding would inform more objective assessments of what further research is required (is further investment in research and development likely to be efficient?) and also permit more accurate economic analyses, since the savings made by averting pressure ulcers would be known.

Only 41 RCTs of support surfaces for pressure ulcer prevention were identified in a recent review and these were largely of poor quality.[33] Much clinical uncertainty therefore remains unaided by high-quality research, and an economic analysis of the expected value of perfect information for alternative research questions would aid research prioritisation.[74]

Research in higher risk groups of patients, in whom serious pressure ulcers are more common and the consequences even greater (e.g. people with spinal cord injuries) is urgently needed; however, such research would inevitably require the collaboration of many clinical centres as these patients are relatively uncommon. Almost nothing is known about risk factors and effective interventions in the highest risk groups. Similarly, there has been no research looking at the impact on quality of life of pressure ulceration in these groups of people.

Future epidemiological studies should attempt to determine whether people with diabetes are more at risk of heel ulceration.

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Contribution of authors

Jane Nixon (Deputy Head, Clinical Trials Research Unit) was clinical coordinator for the trial, a grant co-applicant and took a lead role in protocol development and implementation, CRN support and data monitoring including inter-rater reliability substudies, and contributed to the analysis and the writing of the report. Andrea Nelson (Research Fellow, Department of Health Sciences, University of York) contributed to the design of the trial, led the quality of life study (guarantor for this part of the study) and contributed to the drafting of the report. Gillian Cranny (Medical Statistician, Clinical Trials Research Unit, University of Leeds) participated in meetings, and contributed to the analysis of the data and the writing of the report. Cynthia Iglesias (Health Economist, York Trials Unit, University of York) participated in trial team meetings, performed the economic analysis, prepared manuscripts describing the methods and results of the economic evaluation analysis, and contributed to the writing of the discussion. Kim Hawkins (Head of Statistics, Clinical Trials Research Unit, University of Leeds) participated in meetings, and contributed to the statistical design, statistical analysis and drafting of the report. Nicky Cullum (Professor, Department of Health Sciences, University of York) was Chief Investigator for the trial, a co-applicant who contributed to the conception, design, conduct and monitoring of the trial, and contributed to the analysis and report writing. Angela Phillips (Senior Trial Coordinator, Clinical Trials Research Unit, University of Leeds) contributed to the design and conduct of the trial, was instrumental in the set-up of the database, collection and verification of all data, provided support to all meetings and CTRU support and contact for CRNs, and contributed to the writing of the report. Karen Spilsbury (Research Fellow, Department of Health Sciences, University of York) contributed to the design, conduct, analysis and report writing of the CRNs' focus group. Karen also assisted Andrea Nelson with the quality of life substudy by carrying out some of the patient interviews, analysing the interview transcripts and report writing. David Torgerson (Professor, Department of Health Sciences) was a grant co-applicant, who contributed to the design and conduct of the trial and oversaw the economic evaluation. Su Mason (Principal Research Fellow, Clinical Trials Research Unit, University of Leeds) was a grant co-applicant, contributed to the design and conduct of the trial, was policy manager of the project, chaired meetings on a regular basis to review and manage the progress of the project, and contributed to analysis and the writing of the report.

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Appendix 1

Braden scale

SENSORY PERCEPTION Ability to respond meaningfully to pressure related discomfort	1. Completely limited: Unresponsive (does not moan, flinch or grasp) to painful stimuli, due to diminished level of consciousness or sedation OR limited ability to feel pain.	2. Very limited: Responds only to painful stimuli. Cannot communicate discomfort except by moaning or restlessness OR has a sensory impairment which limits the ability to feel pain or discomfort over 1/2 of body.	3. Slightly limited: Responds to verbal commands but cannot always communicate discomfort or need to be turned OR has some sensory impairment which limits ability to feel pain or discomfort in 1 or 2 extremities.	4. No impairment: Responds to verbal commands. Has no sensory deficit which would limit ability to feel or voice pain or discomfort.
MOISTURE Degree to which skin is exposed to moisture.	1. Constantly moist: Skin is kept moist almost constantly by perspiration, urine, etc. Dampness is detected every time patient is moved or turned.	2. Very moist: Skin is often but not always moist. Linen must be changed at least once a shift.	3. Occasionally moist: Skin is occasionally moist, requiring an extra linen change approximately once a day.	4. Rarely moist: Skin is usually dry, linen only requires changing at routine intervals.
ACTIVITY Degree of physical activity.	1. Bedfast: Confined to bed.	2. Chairfast: Ability to walk severely limited or non-existent. Cannot bear own weight and/or must be assisted into chair or wheelchair.	3. Walks occasionally: Walks occasionally during day but for very short distances, with or without assistance. Spends majority of each shift in bed or chair.	4. Walks frequently: Walks outside the room at least twice a day and inside room at least once every 2 hours during waking hours.
MOBILITY Ability to change and control body position.	1. Completely immobile: Does not make even slight changes in body or extremity position without assistance.	2. Very limited: Makes occasional slight changes in body or extremity position but unable to make frequent or significant changes independently.	3. Slightly limited: Makes frequent though slight changes in body or extremity position independently.	4. No limitation: Makes major and frequent changes in position without assistance.
NUTRITION Usual food intake pattern.	1. Very poor: Never eats a complete meal. Rarely eats more than 1/3 of any food offered. Eats 2 servings or less of protein (meat or dairy products) per day. Takes fluids poorly. Does not take a liquid dietary supplement OR is NPO and/or maintained on clear liquids or IVs for more than 5 days.	2. Probably inadequate: Rarely eats a complete meal and generally eats only about 1/2 of any food offered. Protein intake includes only 3 servings of meat or dairy products per day. Occasionally will take a dietary supplement OR receives less than optimum amount of liquid diet or tube feeding.	3. Adequate: Eats over half of most meals. Eats a total of 4 servings of protein (meat or dairy products) each day. Occasionally will refuse a meal but will usually take a supplement if offered OR is on a tube feeding or TPN regimen which probably meets most of nutritional needs.	4. Excellent: Eats most of every meal. Never refuses a meal. Usually eats a total of 4 or more servings of meat and dairy products. Occasionally eats between meals. Does not require supplementation.
FRICTION AND SHEAR	1. Problem: Requires moderate to maximum assistance in moving. Complete lifting without sliding against sheets is impossible. Frequently slides down in bed or chair, requiring frequent repositioning with maximum assistance. Spasticity, contractures or agitation leads to almost constant friction.	2. Potential problems: Moves feebly or requires minimum assistance. During a move skin probably slides to some extent against sheets, chair, restrains or other devices. Maintains relatively good position in chair or bed most of the time but occasionally slides down.	3. No apparent problem: Moves in bed and in chair independently and has sufficient muscle strength to lift up completely during move. Maintains good position in bed or chair at all times.	

Appendix 2

PRESSURE Trial: patient information sheet

Hospital headed paper

Patient Information Sheet

A Study of Mattresses for Pressure Sore Prevention and Treatment

You are being invited to take part in a research study. Before you decide whether or not to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with relatives and your ward nurse if you wish. Ask us if there is anything that is not clear or if you would like more information.

Whether or not you take part is entirely voluntary. If you do decide to do so, you will be given this information sheet to keep together with a copy of the consent form which you will be asked to sign. You will remain free to withdraw at any time, without giving a reason, and this will not affect any aspect of your ward care. If you do not want to take part this will not affect your ward care.

Background to the study

Pressure sores, also called bedsores, develop in a small number of people admitted to hospital. They have many causes and each patient has a different level of risk. During your stay on the ward, nurses assess your risk of developing bedsores and may provide a 'special mattress' or bed. This research study will compare two types of mattress to see which of the mattresses is best in preventing and treating pressure sores.

By collecting information on patients during their hospital stay we hope to find out which mattress is best. In total we will include 2,100 surgical and medical patients, over a two-year period, who are confined to bed or chair for a period during their hospital stay.

What does this mean for you?

Both mattresses in this study are air mattresses and known as alternating pressure mattresses. The cells in the mattresses inflate and deflate in sequence thereby changing the pressure to different parts of your body.

Which mattress you receive will be decided independently by a computer, which has no information about individual patients (that is, by chance). You have a 50:50 chance of receiving either of the two mattresses. One mattress is placed over the basic hospital mattress (**overlay**) and the other is instead of the basic hospital mattress (**replacement**). You will remain on the allocated mattress until you are discharged from hospital, you are able to move around more or you ask that the mattress be changed.

Ward nurses will assess your skin at least daily and assess your seating, skin care and comfort needs as they would normally as part of ward routine. **In addition the research nurse will visit twice weekly throughout your stay to assess the skin on your buttocks, heels and hips, and ask questions about how much you can move, how you are eating, your general well-being, and whether the mattress is comfortable.**

The research nurse will record your details including your name, date of birth, hospital number and consultant, ward, results from routine blood tests, skin assessments and factors known to increase the risk of getting a bedsore, such as how well you move and eat.

If you already have a bedsore or develop a bedsore the research nurse or ward nurse will measure it weekly by drawing around the area onto a clear dressing sheet. This will be done only when your ward nurse plans to change your dressing. Ward nurses will also record the dressings they use on the bedsore and may time how long it takes to change your dressing. You may be asked how the bedsore has affected your daily life and recovery from illness. In the event that you have a district nurse when you are discharged from hospital he/she will be asked how many visits were made to you at home to re-dress the bedsore.

Alternative mattresses

The alternative mattress is a standard foam mattress, which you can request if you are unhappy with the alternating mattress. On very rare occasions patients are provided with very 'high-tech' bead or air beds. The decision that you need such a bed would be made by the nurses and doctors responsible for your care and you would be withdrawn from the research on their advice.

Disadvantages

The mattresses in this research study are in common use. Very rarely patients report feeling uncomfortable on the mattresses – if this happens, you can ask for the mattress to be changed to something which better suits your needs.

The mattresses can sometimes cause problems for patients getting in and out of bed. They also raise the height of the bed compared to a standard foam mattress increasing the risk of harm from falls from bed. In such circumstances, as with normal practice, ward nurses would be responsible for your safety and changing the mattress for one that better suits your needs.

Benefits

The advantage of the mattresses is that they might help prevent you getting a bedsore.

If new information becomes available

Sometimes, during the course of a research study, new information becomes available about the treatment being studied. If this happens, your research nurse will tell you about it and discuss with you whether you want to continue in the study. If you decide to withdraw from the study you will be able to do so. If you decide to remain in the study you will be asked to sign an updated consent form.

If the study is stopped

A research committee, which includes independent advisors, will meet regularly during the study. If new information becomes available and the committee decides to stop the research, your research nurse will inform you of this and provide a full explanation.

What if something goes wrong

The ward nurses remain responsible for your care during your hospital stay. If they are unhappy about the mattress you are on, they are able to change it for one that better suits your needs.

If you wish to complain about any aspect of the way in which you have been approached or treated during the course of this study, the normal National Health Service complaints procedure should be followed. Please ask your Ward Sister/Charge Nurse for details or contact your hospital's Complaints Office on Tel: …….. (*hospital complaints office number to be inserted*).

Confidentiality

If you consent to take part in the research, your medical and nursing records may be inspected by the research staff for data relevant only to the research. If you are discharged home with a pressure sore and you also have a district nurse, his/her records will be reviewed. This will require the research nurse recording the name and address of you, your GP and your district nurse. You <u>will not</u> be contacted after your discharge from hospital.

All the information collected about you during the course of the research will be strictly confidential and will abide by the 1998 Data Protection Act.

Administrative details

The 'National Health Service Research and Development Programme – Health Technology Assessment' has commissioned this study. The funding has provided your hospital with some extra mattresses for clinical use and the employment of a research nurse to co-ordinate data collection. The results of the study will be available in 2004 on the following web site: http://www.hta.nhsweb.nhs.uk

The research study has been approved by the North West Multicentre Research Ethics Committee.

Thank you for considering this study. If you have any questions or require further information please contact:

Research Sister Telephone Bleep

Appendix 3

PRESSURE Trial: relatives' information sheet

Hospital headed paper

Patient Relative Information Sheet

A Study of Mattresses for Pressure Sore Prevention and Treatment

You are being asked to allow your relative to take part in a research study. Before you decide whether or not your relative can take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with your other relatives and ward staff if you wish. Ask us if there is anything that is not clear or if you would like more information.

Whether or not you agree for your relative to take part is entirely voluntary. If you do agree, you will be given this information sheet to keep together with a copy of the consent form which you will be asked to sign. You will remain free to withdraw your relative at any time, without giving a reason, and this will not affect any aspect of their ward care. If you do not want your relative to take part this will not affect their ward care.

Background to the study

Pressure sores, also called bedsores, develop in a small number of people admitted to hospital. They have many causes and each patient has a different level of risk. During your relative's stay on the ward, nurses assess the risk of bedsores developing and may provide a 'special mattress' or bed. This research study will compare two types of mattress to see which of the mattresses is best in preventing and treating pressure sores.

By collecting information on patients during their hospital stay we hope to find out which mattress is best. In total we will include 2,100 surgical and medical patients, over a two-year period, who are confined to bed or chair for a period during their hospital stay.

What does this mean for your relative?

Both mattresses in this study are air mattresses and known as alternating pressure mattresses. The cells in the mattresses inflate and deflate in sequence thereby changing the pressure to different parts of the body.

Which mattress your relative will receive will be decided independently by a computer, which has no information about individual patients (that is, by chance). Your relative will have a 50:50 chance of receiving either of the two mattresses. One mattress is placed over the basic hospital mattress (**overlay**) and the other is instead of the basic hospital mattress (**replacement**). Your relative will remain on the allocated mattress until discharged from hospital, or until they are able to move around more or you ask that the mattress be changed.

Ward nurses will assess your relative's skin at least daily and assess skin care and comfort needs as they would normally as part of ward routine. **In addition the research nurse will visit twice weekly to assess the skin on their buttocks, heels and hips, and ask ward staff questions about their movement, nutrition and general condition.**

The research nurse will record your relative's details including name, date of birth, hospital number and consultant, ward, results from routine blood tests, skin assessments and factors known to increase the risk of getting a bedsore, such as movement.

If your relative already has a bedsore or develops a bedsore the research nurse or ward nurse will measure it weekly by drawing around the area onto a clear dressing sheet. This will be done only when the ward nurse plans to change the dressing and will not cause further disturbance to your relative. Ward nurses will also record the dressings they use on the bedsore and may time how long it takes to change the dressing.

Alternative mattresses

The alternative mattress is a standard foam mattress, which you can request for your relative if you are unhappy with the alternating mattress. On very rare occasions patients are provided with very 'high-tech' bead or air beds. The decision that your relative needs such a bed would be made by the ward nurses and doctors. If a 'high-tech' bead or air bed is required for your relative they would receive this and be withdrawn from the research.

Disadvantages

The mattresses in this research study are in common use. Very rarely patients report feeling uncomfortable on the mattresses – if this happens, the mattress can be changed.

The mattresses can sometimes cause problems for patients getting in and out of bed. They also raise the height of the bed compared to a standard foam mattress, increasing the risk of harm from falls from bed. In such circumstances, as with normal practice, ward nurses would be responsible for the safety of your relative and would be free to change the mattress for one that better suits your relative's needs.

Benefits

The advantage of the mattresses is that they might help prevent your relative from getting a bedsore.

If new information becomes available

Sometimes, during the course of a research study, new information becomes available about the treatment being studied. If this happens, the research nurse will tell you about it and discuss with you whether you want your relative to continue in the study. If you decide to withdraw your relative from the study you will be able to do so. If you decide that your relative should remain in the study you will be asked to sign an updated consent form.

If the study is stopped

A research committee, which includes independent advisors, will meet regularly during the study. If new information becomes available and the committee decides to stop the research, the research nurse will inform you of this and provide a full explanation.

What if something goes wrong

The ward nurses remain responsible for your relative's care during your hospital stay. If they are unhappy about the mattress, they are able to change it for one that better suits the needs of your relative.

If you wish to complain about any aspect of the way in which you have been approached or treated during the course of this study, the normal National Health Service complaints procedure should be followed. Please ask the Ward Sister/Charge Nurse for details or contact the hospital Complaints Office via telephone number …….. (*hospital complaints office number to be inserted*).

Confidentiality

If you assent for your relative to take part in this research, their medical and nursing records may be inspected by the research staff for data relevant only to the research. All the information collected about your relative during the course of the research will be strictly confidential and will abide by the 1998 Data Protection Act.

Administrative details

The 'National Health Service Research and Development Programme – Health Technology Assessment' has commissioned this study. The funding has provided the hospital with some extra mattresses for clinical use and the employment of a research nurse to co-ordinate data collection. The results of the study will be available in 2004 on the following web site: http://www.hta.nhsweb.nhs.uk

The research study has been reviewed by the North West Multicentre Research Ethics Committee.

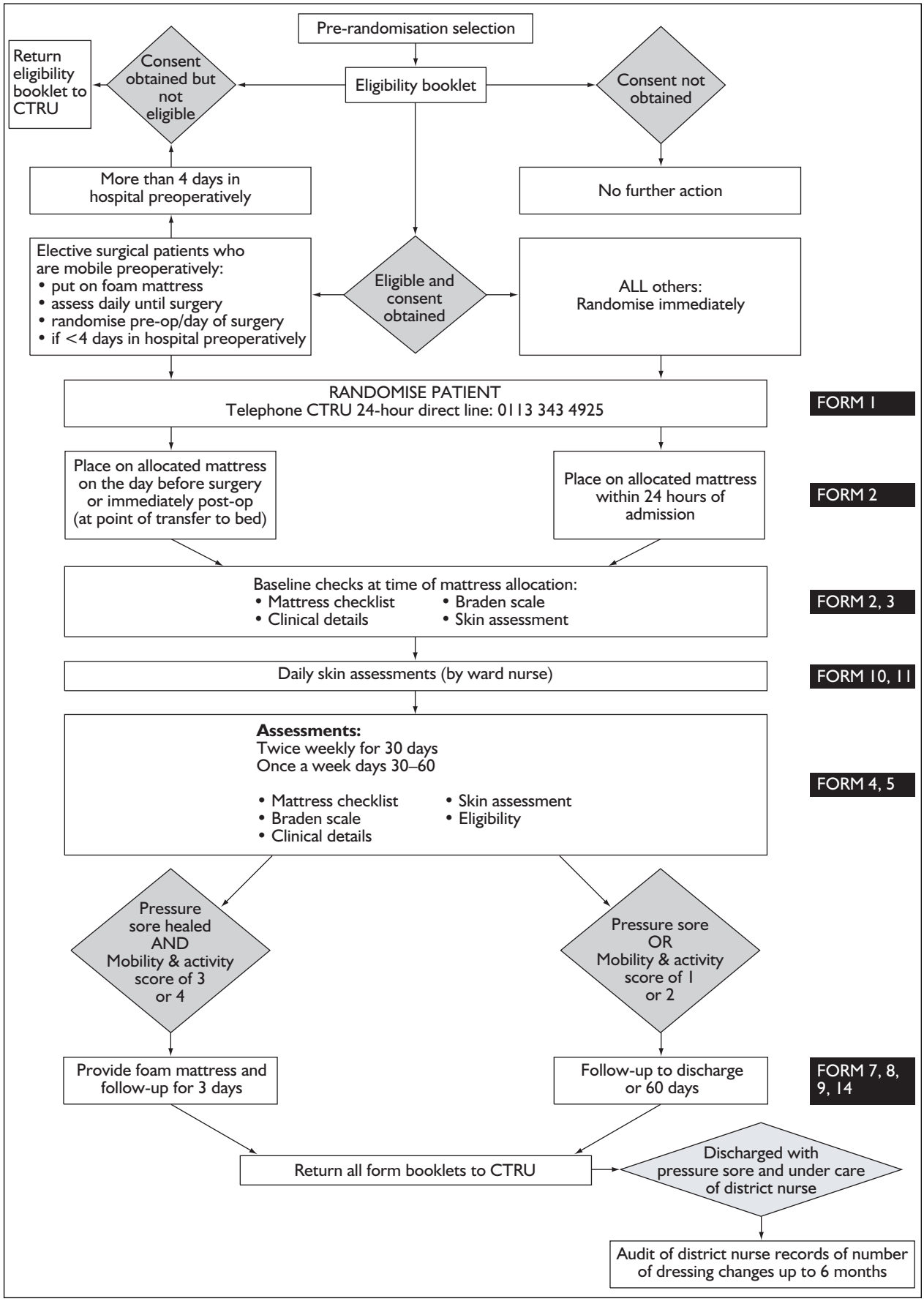
Thank you for considering this study. If you have any questions or require further information please contact:

Research Sister Telephone Bleep

Appendix 4

PRESSURE Trial: flow diagram

All assessments to be completed by Research Nurse or designated Ward Nurse (unless indicated)



Appendix 5

Trial steering committee

External experts and DMEC members

Professor Jenny Hewison (Independent Chair)
Professor of Healthcare Psychology
Academic Unit of Psychiatry and Behavioural Sciences
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Professor David Machin
Professor of Clinical Trials Research
Institute of General Practice & Primary Care
School of Health and Related Sciences
University of Sheffield
Sheffield

Dr Gerben ter Riet
Clinical Epidemiologist
Academic Medical Center
Department of General Practice
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The Netherlands

Project team

Professor Nicky Cullum
Director
Centre for Evidence-Based Nursing
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University of York
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Miss Kim Hawkins (also in attendance at DMEC)
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Clinical Trials Research Unit
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17 Springfield Mount
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Dr Su Mason (also in attendance at DMEC)
Principal Research Fellow
Clinical Trials Research Unit
University of Leeds
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Dr E. Andrea Nelson
Senior Research Fellow
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Dr Jane Nixon
Deputy Director
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Mrs Angela Phillips (also in attendance at DMEC)
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Miss Gillian Cranny
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Director
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University of York
York YO10 5DD

Miss Cynthia Iglesias (also in attendance at DMEC)
Research Fellow
Department of Health Sciences/Centre for Health Economics
Alcuin Teaching Building
University of York
York YO10 5DD

Appendix 6

Trial Steering Committee Terms of Reference

The Terms of Reference of the Steering Committee are as follows:

1. To provide overall supervision for the trial.
2. To monitor and supervise the progress of the trial towards its overall objectives, adherence to the protocol and patient accrual within the set time-frame.
3. To review at regular intervals relevant information from other sources (e.g. other related trials) and recommend appropriate action (e.g. changes to trial protocol, stopping or extending the trial).
4. To recommend appropriate action in light of points 1, 2 and 3 to ensure that the rights, safety and well-being of the trial participants are the most important considerations and prevail over the interests of science and society.

Appendix 7

Trial Management Group

Research applicants

Professor Nicky Cullum	Chief Investigator
Dr Jane Nixon	Clinical Coordinator
Dr Su Mason	Trial Policy Manager
Dr E. Andrea Nelson	Lead for quality of life substudy
Professor David Torgerson	Lead for health economic substudy

CTRU, University of Leeds

Miss Kim Hawkins	Head Statistician for main clinical study
Miss Gillian Cranny	Statistician for main clinical study
Mrs Angela Phillips	Senior Trial Coordinator
Miss Gillian Eddison	Trial Coordinator

Department of Health Sciences, University of York

Cynthia Iglesias	Research Fellow for health economic substudy
Dr Karen Spilsbury	Research Fellow for focus group substudy and quality of life substudy

Leeds Teaching Hospitals

Helen Barrow	Clinical Research Nurse Team Leader

(See Appendix 5 for contact details.)

Appendix 8

External Project Team: Trust Leads and Clinical Research Nurses

Trust Leads	Clinical Research Nurses
Leeds Teaching Hospitals NHS Trust	
Mrs Cathy Winn	Helen Barrow
Head of Nursing Policy and Practice Development	Caroline Cooper
Corporate Nursing	Fiona Corcoran
Old School of Health Care Studies	Patricia Hutchinson
St James's University Hospital	Yvonne Meades
Beckett Street	Dawn Parkes
Leeds LS9 7TF	Fiona Smith
York Health Services NHS Trust	
Mrs Joyce Sims	Ann Fotheringham
Tissue Viability Nurse	Sarah Gowland
York District Hospital	Ann Warriner
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Bradford Teaching Hospitals NHS Trust	
Ms Maria Neary	Patricia Hutchinson
Head of Practice Development	
Bradford Hospitals NHS Trust	
St Luke's Hospital	
Little Horton Road	
Bradford BD5 0NA	
Aintree Hospitals NHS Trust	
Ms Monica Moore	Caroline Smith
Tissue Viability Nurse Specialist	
1st Floor, Clinical Sciences Centre	
University Hospital Aintree	
Longmoor Lane	
Liverpool L9 7AL	
North Tees and Hartlepool NHS Trust	
Dr Eileen Scott	Richard Buckland
R&D Coordinator	Monica Clark
Clinical Development Unit	Morag Doherty
2nd Floor Maternity	Andrew Young
North Tees General Hospital	
Stockton-on-Tees TS19 8PE	
Scarborough and North East Yorkshire Healthcare Trust	
Mrs Jane Jones	Helen Marson
Tissue Viability Nurse	
Scarborough Hospital	
Woodlands Drive	
Scarborough YO12 6QN	

Appendix 9

PRESSURE Trial: Patient Consent Form

(Form to be on headed paper)

Centre Number:
Study Number:
Patient Identification Number: *Initials and Date of Birth*

PATIENT CONSENT FORM

Title of Project: Pressure Trial – A study of Mattresses for Pressure Sore Prevention and Treatment

Name of Researcher: *Research Nurse*

	Please initial box
1. I confirm that I have read and understand the information sheet dated ..... (version .....) for the above study and have had the opportunity to ask questions.	☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.	☐
3. I understand that sections of any of my medical notes may be looked at by responsible individuals from [NHS Trust] or from regulatory authorities where it is relevant to my taking part in research. I give permission for these individuals to have access to my records.	☐
4. I agree to take part in the above study.	☐

Name of Patient	Date	Signature
Name of Nurse taking consent (*if different from research nurse*)	Date	Signature
Research Nurse	Date	Signature

1 for patient; 1 for researcher; 1 to be kept with hospital notes

Appendix 10

Assent by Relative Consent Form

(Form to be on headed paper)

Centre Number:
Study Number:
Patient Identification Number: *Initials and Date of Birth*

CONSENT FORM – ASSENT BY RELATIVE

Title of Project: Pressure Trial – A Study of Mattresses for Pressure Sore Prevention and Treatment

Name of Researcher: *Research Nurse*

	Please initial box
1. I confirm that I have read and understand the information sheet dated ..... (version .....) for the above study and have had the opportunity to ask questions.	☐
2. I understand that my relative's participation is voluntary and that I am free to withdraw them at any time, without giving any reason, without their medical care or legal rights being affected.	☐
3. I understand that sections of any of my relative's medical notes may be looked at by responsible individuals from [NHS Trust] or from regulatory authorities where it is relevant to them taking part in research. I give permission for these individuals to have access to my relative's records.	☐
4. I agree for my relative to take part in the above study.	☐

Name of Patient	Name of Next of Kin	Relationship to Patient
	Date	Signature of Next of Kin
Research Nurse	Date	Signature

1 for patient; 1 for researcher; 1 to be kept with hospital notes

Appendix 11

Schedule of monitoring and source data verification

Monitoring

Level 1
Clinical research nurses check all forms before return to the NYCTRU.

Level 2
Senior trial coordinator – assessment of all forms on receipt and immediate follow-up of missing data items.

Senior trial coordinator – assessment of all consent forms on receipt and signature comparisons within centres.

Level 3
Clinical coordinator – review all forms for patients with pressure sores (on entry to trial or developed during the trial) and at least three other sets of forms received from each centre on a monthly basis.

Level 4
Trial coordinator – data entry validation and data checking follow-up.

Level 5
Project team – quarterly review of recruitment, adverse events and withdrawals.

Level 6
Independent blind verification of unclear end-points.

Level 7
Trial steering committee – 6-monthly review of:

- recruitment
- adverse events
- problems arising – non-trial
  – postrandomisation
- consent/assent procedures
- acute/elective breakdown
- withdrawal
- mattress changes (number and reasons)
- data quality (including missing data on form 10)
- inter-rater reliability.

Level 8
Data monitoring committee – 6-monthly review of:

- adverse events by allocation
- deaths by allocation and mattress at time of death (from April 2003).

Monitoring feedback
Feedback to individual clinical research nurses (CRN) by telephone or e-mail and general feedback to all by e-mail. Recurrent problems identified by senior trial coordinator and clinical coordinator for discussion at CRN team meetings (quarterly) and project team meetings (monthly).

Data verification

Clinical research nurse coordinator – site visits quarterly to verify:

10% patient records following completion of the trial including verification of: patient title and initials, DOB, hospital number, date of admission and speciality.

Appendix 12

Data monitoring: the reliability of pressure ulcer diagnosis and classification

Introduction

To monitor the quality of data recorded by the PRESSURE clinical research nurses (CRNs) and qualified ward nursing staff (WNs), and aid the decision regarding which data to use in the final analysis of the pressure ulcers study (that is, CRN or WN data), inter-rater reliability was assessed. The aim was to determine the inter-rater reliability of data relevant to the derivation of the primary end-point (the development of a new pressure ulcer) and secondary end-points, including time to development of new ulcers, the maximum grade of new pressure ulcers and time to healing. It was important, therefore, to assess the reliability of the diagnosis of a pressure ulcer (grade 2 or above) and skin classification for all grades (secondary end-points and secondary analysis).

Inter-rater reliability was assessed:

- between the CRN coordinator and CRNs working across different hospital sites:
  - pretrial CRN inter-rater reliability substudy
  - new CRN inter-rater reliability assessments
  - repeat CRN inter-rater reliability assessments
- between CRNs and WNs.
  - pretrial inter-rater reliability substudy
  - trial data inter-rater reliability assessment.

CRN coordinator and CRN agreement

Pretrial CRN inter-rater reliability substudy

During the set-up period a pretrial inter-rater reliability study was undertaken. Patients from medical, elderly care, orthopaedic and vascular surgical wards across eight hospital sites (four NHS trusts) were invited to participate in the study by the PRESSURE Trial CRNs. Patients aged over 18, bedfast or chairfast on the day of the CRN ward visit and able to provide consent, were invited to participate. Paired patient assessments were undertaken and skin was assessed on seven body sites including the sacrum, left and right buttocks, left and right hips, and left and right heels. Assessed skin was graded using the classification scale detailed in *Table 2* (Chapter 2).

Statistical methods

To assess the inter-rater reliability of the pressure ulcer diagnosis, the percentage agreement between nurses in grading a skin site with either a pressure ulcer (≥ grade 2) or no pressure ulcer (grade 0, 1a and 1b) was determined and the kappa statistic calculated. To assess the inter-rater reliability of skin classification for all grades, assessments for all skin sites were pooled and percentage agreement between nurses in classifying skin for all grades (grades 0, 1a, 1b, 2, 3, 4 and 5) was determined.

As a test statistic kappa can verify that agreement exceeds the level of agreement that is likely to happen by chance. Kappa requires independence of patients and is influenced by the prevalence within categories. Chance agreement is more likely to happen if there is a small number of assessors classifying a small number of skin areas. Therefore, patients were only included in the study on one occasion, and the inclusion criteria aimed to obtain a patient sample that included at least one in four patients with an existing pressure ulcer of (≥ grade 2).

Reporting percentage agreement is also important because kappa is dependent on the prevalence of the categories, and values of kappa generated from different studies are not easily comparable.[87] Assessments for the seven skin sites were analysed separately assuming each skin site to be independent and strength of agreement was categorised using established guidelines (*Table 59*). Assessments were also pooled and analysed overall.

TABLE 59 *The kappa statistic*[87]

Value of kappa (κ)	Strength of agreement
<0.20	Poor
0.21–0.40	Fair
0.41–0.60	Moderate
0.61–0.80	Good
0.81–1.00	Very good

TABLE 60 *Pressure ulcer diagnosis: CRN team leader and CRN agreement (pretrial substudy)*

Skin site	% Agreement	κ
Sacrum	100% (16/16)	–[a]
Left buttock	100% (16/16)	1.0
Right buttock	100% (16/16)	1.0
Left heel	100% (14/14)	1.0
Right heel	100% (16/16)	1.0
Left hip	100% (14/14)	–[a]
Right hip	100% (15/15)	–[a]
All areas	100% (107/107)	1.0

[a] A kappa statistic is not given for these particular skin sites as all nurses graded patients as having no pressure ulcer; hence, there is only one non-zero level in the 2 × 2 table.

Training

The CRNs were all experienced clinical nurses with a range of experience, at least 3 years' postregistration experience in elderly care, medical, vascular surgery or orthopaedic nursing, and an interest in tissue viability. They were provided with additional training and education in skin assessment using the skin classification scale (*Table 2*, Chapter 2). This included provision of the study protocol, published articles detailing the skin classification scale and clinical assessment methods, participation in a 2-day training programme during study set-up (including discussion of skin assessment and issues of reliability) and one-to-one discussion with the CRN team leader.

Data collection

The CRN team leader made a planned site visit and, together with the CRN, recruited patients from the research wards including elderly, medical, orthopaedic and vascular inpatients. Permission to approach patients was given by the ward nurse-in-charge. Information about the study was provided to patients by the CRN or CRN team leader and patient consent obtained before participation.

Skin inspection was performed simultaneously by both assessors, but recorded separately. Up to four patients were assessed by both nurses, and where possible this included at least one patient with a pressure ulcer. The CRN team leader returned all pro formas for analysis.

Results

In total, 16 paired assessments were undertaken between the CRN team leader and four CRNs during the period from December 2000 to February 2001. This generated data for 112 site comparisons and, excluding site comparisons with missing data (owing to the presence of dressings or limb amputation, for example), resulted in a final sample of 107 site comparisons on 16 patients.

Pressure ulcer diagnosis

The percentage agreement in the diagnosis of a pressure ulcer between nurses, and corresponding kappa statistics for the seven skin sites and overall are presented in *Table 60*. There was 100% agreement for all skin sites between the CRN team leader and the four CRNs, and the kappa statistics indicate 'very good' agreement for all sites in relation to the assessment of pressure ulcer/no pressure ulcer. Confidence intervals for the kappa statistics are not reported owing to the 100% agreement between the CRNs, resulting in standard errors of zero for each kappa statistic, and hence the upper and lower 95% confidence limits for each statistic are equal to 1.0.

Skin classification: all grades

Agreements between the CRN team leader and CRNs for the 107 paired site assessments are detailed in *Table 61*. There was a total of two

TABLE 61 *Skin classification, all grades: CRN team leader; and CRN agreement, all sites (pretrial substudy)*

		CRN assessment							
	Grade	0	1a	1b	2	3	4	5	Total
	0	47	0	0	0	0	0	0	47
CRN	1a	1	30	0	0	0	0	0	31
team	1b	0	1	18	0	0	0	0	19
leader	2	0	0	0	6	0	0	0	6
assessment	3	0	0	0	0	4	0	0	4
	4	0	0	0	0	0	0	0	0
	5	0	0	0	0	0	0	0	0
Total		48	31	18	6	4	0	0	107

TABLE 62 *Pressure ulcer diagnosis: CRN team leader and CRN agreement (new CRNs)*

Skin site	% Agreement	No. of sites graded as pressure ulcer	κ
Sacrum	100% (35/35)	2	1.00
Left buttock	100% (34/34)	3	1.00
Right buttock	100% (35/35)	4	1.00
Left heel	100% (34/34)	0	–[a]
Right heel	100% (33/33)	1	1.00
Left hip	100% (30/30)	0	–[a]
Right hip	100% (32/32)	0	–[a]
All sites	100% (233/233)	10	1.00

[a] A kappa statistic is not given here as all nurses graded patients as having no pressure ulcer, hence there is only one non-zero level in the 2 × 2 table.

TABLE 63 *Skin classification, all grades: CRN team leader; and CRN agreement, all sites (new CRNs)*

		CRN assessment							
	Grade	0	1a	1b	2	3	4	5	Total
	0	129	3	0	0	0	0	0	132
CRN	1a	2	59	3	0	0	0	0	64
team	1b	0	5	22	0	0	0	0	27
leader	2	0	0	0	9	0	0	0	9
assessment	3	0	0	0	0	1	0	0	1
	4	0	0	0	0	0	0	0	0
	5	0	0	0	0	0	0	0	0
Total		131	67	25	9	1	0	0	233

(1.9%) disagreements between the CRN team leader and CRNs. Both disagreements were only one grade different: grades 0 and 1a (1), 1a and 1b (1). It is noteworthy that the areas of disagreement between the CRN team leader and CRNs were in relation to the assessment of normal skin, blanching and non-blanching erythema.

These data were presented to the TSC on 24 April 2002.

New CRN inter-rater reliability assessments

Using the methodology detailed above (Pretrial CRN inter-rater reliability substudy), inter-rater reliability assessments were undertaken between the CRN team leader and all new CRNs appointed during the study period.

Results

In total, 35 paired assessments were undertaken between the CRN team leader and nine CRNs. This generated data for 245 site comparisons and, excluding site comparisons with missing data (owing to the presence of dressings or limb amputation, for example), resulted in a final sample of 233 site comparisons on 35 patients.

Pressure ulcer diagnosis

The percentage agreement in the diagnosis of a pressure ulcer between nurses, and corresponding kappa statistics for the seven skin sites and overall are presented in *Table 62*. There was 100% agreement for all skin sites between the CRN team leader and the nine CRNs, and the kappa statistics indicate 'very good' agreement for all sites in relation to the assessment of pressure ulcer/no pressure ulcer. Confidence intervals for the kappa statistics are not reported owing to the 100% agreement between the CRNs, resulting in standard errors of zero for each kappa statistic, and hence the upper and lower 95% confidence limits for each statistic are equal to 1.0.

Skin classification: all grades

Agreements between the CRN team leader and new CRNs for the 233 paired site assessments are detailed in *Table 63*. There was a total of 13 (5.6%) disagreements between the CRN team leader and CRNs. All disagreements were only one grade different: grades 0 and 1a (5), 1a and 1b (8).

Repeat CRN inter-rater reliability assessments

Using the methodology detailed above (Pretrial

TABLE 64 *Pressure ulcer diagnosis: CRN team leader and CRN agreement (repeats)*

Skin site	% Agreement	No. of sites graded as pressure ulcer	κ
Sacrum	100% (19/19)	3	1.00
Left buttock	100% (19/19)	0	–[a]
Right buttock	100% (19/19)	0	–[a]
Left heel	100% (19/19)	1	1.00
Right heel	100% (19/19)	1	1.00
Left hip	100% (20/20)	0	–[a]
Right hip	100% (19/19)	0	–[a]
All sites	100% (134/134)	5	1.00

[a] A kappa statistic is not given here as all nurses graded patients as having no pressure ulcer, hence there is only one non-zero level in the 2 × 2 table.

TABLE 65 *Skin classification, all grades: CRN team leader; and CRN agreement, all sites (repeats)*

		CRN assessment							
	Grade	0	1a	1b	2	3	4	5	Total
	0	73	6	0	0	0	0	0	79
CRN	1a	3	40	0	0	0	0	0	43
team	1b	0	1	6	0	0	0	0	7
leader	2	0	0	0	3	0	0	0	3
assessment	3	0	0	0	0	0	0	0	0
	4	0	0	0	0	0	0	0	0
	5	0	0	0	0	0	0	2	2
Total		76	47	6	3	0	0	2	134

CRN inter-rater reliability substudy), where CRNs were in post for periods of more than 1 year, inter-rater reliability assessments were repeated annually.

Results

In total, 20 paired assessments were undertaken between the CRN team leader and five CRNs during the recruitment period. This generated data for 140 site comparisons and, excluding site comparisons with missing data (owing to the presence of dressings or limb amputation, for example), resulted in a final sample of 134 site comparisons on 20 patients.

Pressure ulcer diagnosis

The percentage agreement in the diagnosis of a pressure ulcer between nurses, and corresponding kappa statistics for the seven skin sites and overall are presented in *Table 64*. There was 100% agreement for all skin sites between the CRN team leader and the 15 CRNs, and the kappa statistics indicate 'very good' agreement for all sites in relation to the assessment of pressure ulcer/no pressure ulcer. Confidence intervals for the kappa statistics are not reported owing to the 100% agreement between the CRNs, resulting in standard errors of zero for each kappa statistic, and hence the upper and lower 95% confidence limits for each statistic are equal to 1.0.

Skin classification: all grades

Agreements between the CRN team leader and new CRNs for the 134 paired site assessments are detailed in *Table 65*. There was a total of 10 (7.5%) disagreements between the CRN team leader and CRNs. All disagreements were only one grade different: grades 0 and 1a (9), 1a and 1b (1).

Summary: CRN coordinator and CRN agreement

While a limitation of the study is that the high level of agreement is dominated by a high prevalence of 'no pressure ulcer', the associated kappa statistic of 'very good' suggests that the observed agreement for the diagnosis of a pressure ulcer (≥ grade 2) exceeds the level of agreement that is likely to happen by chance. The good levels of agreement between the CRN team leader and CRNs suggest that the CRNs are able to assess skin clinically, and identify and record the presence of a pressure ulcer (i.e. the primary end-point) in a consistent and reliable way. The data collected during the recruitment period suggest

TABLE 66 *Pressure ulcer diagnosis: CRN and WN agreement (pretrial substudy)*

Skin site	% Agreement	κ	95% CI
Sacrum	95.3% (322/338)	0.80	(0.70 to 0.89)
Left buttock	93.6% (334/357)	0.67	(0.55 to 0.80)
Right buttock	93.8% (334/356)	0.62	(0.48 to 0.77)
Left heel	96.5% (333/345)	0.78	(0.66 to 0.90)
Right heel	99.1% (342/345)	0.95	(0.89 to 0.99)
Left hip	100% (330/330)	1.00	(1.00 to 1.00)
Right hip	99.7% (324/325)	0.67	(0.05 to 0.99)
All areas	96.8% (2319/2396)	0.77	(0.72 to 0.82)

that training was maintained by the CRN team leader and that there was no 'drift' in the clinical assessment skills of the new or long-serving CRNs.

In relation to the secondary end-points and agreement for all skin grades, the disagreements observed between the CRN team leader and the CRNs were all associated with the assessment of normal skin, blanching erythema and non-blanching erythema, illustrating the difficulties associated with assessment of skin erythema even when undertaken by expert nurses. The lack of consistency in the assessment of skin erythema justifies the definition of the PRESSURE Trial primary end-point of ≥ grade 2.

CRN and WN agreement

Pretrial inter-rater reliability substudy

Using the methodology detailed above (Pretrial CRN inter-rater reliability substudy), inter-rater reliability assessments were undertaken between the CRNs and WNs during the prestudy period.

Training

WN preparation included one-to-one or small group explanations of the study's skin classification scale by the CRNs, emphasising differences from any scale in clinical use. Information about the study was provided for each ward, including a study protocol, a poster including details of the study and a poster detailing the skin classification scale, including a description and photographs for each grade.

Data collection

The CRNs made planned ward visits to assess four patients with each WN, who had received an explanation of both the study and skin assessment scale and had agreed to participate in the pretrial inter-rater reliability study. Patient recruitment and assessments were undertaken as detailed above and the CRNs returned all pro formas for analysis.

Results

In total, 362 paired assessments were undertaken between six CRNs and 109 WNs during the period from December 2000 to February 2001. This generated data for 2534 site comparisons and, excluding site comparisons with missing data (owing to the presence of dressings or limb amputation, for example), resulted in a final sample of 2396 site comparisons on 109 patients.

Pressure ulcer diagnosis

The percentage agreement in the diagnosis of a pressure ulcer between nurses, and corresponding kappa statistics for the seven skin sites and overall are presented in *Table 66*. There was 93.6–100% agreement between the CRNs and WNs. The kappa statistics calculated indicate 'good' and 'very good' agreement. The 95% confidence intervals for the kappa statistics are reported and, in general, they confirm 'moderate' to 'very good' agreement. However, owing to the large sample some confidence intervals are narrow; conversely, owing to the prevalence of the categories some confidence intervals are extremely wide (e.g. right hip) and therefore interpretation of the kappa statistics is difficult.

Of the 2396 paired site assessments there were 77 (3.2%) disagreements between the CRNs and WNs in relation to the diagnosis of pressure ulcer (*Table 67*). The 77 disagreements were observed on 50 patients, 13.8% of patients assessed by the CRNs and WNs. Disagreements included both nurses recording a pressure ulcer but at different sites such as buttock and sacrum, left hip and right hip (seven patients); the CRN recording a pressure ulcer when the WN did not (24 patients); the WN recording a pressure ulcer when the CRN did not (14 patients); and both nurses recording a pressure ulcer, but one nurse recording more than one ulcer (five patients). The disagreements were observed for all skin sites, apart from left hip, and there were fewer disagreements observed on hip

TABLE 67 *Pressure ulcer diagnosis: CRN and WN agreement (pretrial substudy)*

		WN		
		No pressure ulcer	**Pressure ulcer**	**Total**
CRN	No pressure ulcer	2175 (90.8%)	35 (1.5%)	2210
	Pressure ulcer	42 (1.8%)	144 (6.0%)	186
	Total	2217	179	2396

TABLE 68 *Skin classification, all grades: CRN; and WN agreement, all sites (pretrial substudy)*

		WN assessment							
	Grade	**0**	**1a**	**1b**	**2**	**3**	**4**	**5**	**Total**
	0	1239	92	10	7	0	0	0	1348
	1a	187	442	65	21	1	0	0	716
CRN	1b	11	47	82	6	0	0	0	146
assessment	2	6	25	8	95	5	0	2	141
	3	1	2	0	6	14	2	0	25
	4	0	0	0	0	1	1	0	2
	5	0	0	0	2	1	0	15	18
Total		1444	608	165	137	22	3	17	2396

and heel areas compared with buttocks and sacrum (*Table 66*).

The 77 disagreements were associated with 38 different WNs and, of these, 16 staff recorded one disagreement, eight staff recorded two disagreements, 11 recorded three disagreements and three recorded four disagreements.

Skin classification: all grades

Agreements between the CRNs and WNs for the 2396 paired site assessments for all grades are detailed for all body sites in *Table 68*. There was a total of 508 (21.2%) disagreements between the CRNs and WNs. Of the 508 disagreements, 419 were one grade different (0 and 1a, 1a and 1b, etc.), 68 were two grades different, including 0 and 1b (21), 1a and 2 (46) and 3 and 5 (1), and 21 were more than two grades different, including 0 and 2 (13), 0 and 3 (1), 1a and 3 (3), 2 and 5 (4).

Trial data inter-rater reliability assessment

A comparison of the 'grading' of pressure ulcers throughout the study was undertaken using follow-up data recorded by WNs and CRNs.

Throughout the study, WNs were asked to assess skin on a daily basis and record the clinical observations using the PRESSURE Trial skin classification for seven body sites, including sacrum, left and right buttock, left and right heel and left and right hip, using case record form 10. The CRNs assessed skin twice weekly and recorded clinical observations using case record form 4.

Data extraction/statistical methods

The analyses included all patients who had completed the study up to the end of December 2002. Skin assessment records for the first and last CRN visit were extracted for each patient and the corresponding WN assessments were extracted for the same dates. The level of agreement was presented to the TSC in three formats:

- combining the first and last CRN assessment dates
- the first CRN assessment date
- the last CRN assessment date.

To assess the inter-rater reliability of pressure ulcer diagnosis, the percentage agreement between nurses in grading a skin site with either a pressure ulcer (≥ grade 2) or no pressure ulcer (grade 0, 1a and 1b) was determined. To assess the inter-rater reliability of skin classification for all grades, assessments for all skin sites were pooled and percentage agreement between nurses in classifying skin for all grades (grades 0, 1a, 1b, 2, 3, 4 and 5) was determined. Kappa (κ) was not undertaken as it would provide little additional information given the low incidence of pressure ulcers (i.e. any estimate of κ will have wide confidence intervals).

TABLE 69 *Pressure ulcer diagnosis: CRN and WN agreement (trial data)*

CRN assessment	Daily WN assessment		
	No pressure ulcer	Pressure ulcer	Total
No pressure ulcer	2548 (97.8%)	12 (0.5%)	2560
Pressure ulcer	15 (0.6%)	31 (1.2%)	46
Total	2563	43	2606

TABLE 70 *Skin classification, all grades: CRN; and WN agreement, all sites (trial data)*

CRN assessment	Daily WN assessment							
	Missing	0	1a	1b	2	3	4	5	Total
Missing	175	143	11	1	5	1	2	0	338
0	856	1770	107	13	0	0	0	0	2746
1a	207	343	177	16	7	0	0	0	750
1b	50	42	41	39	5	0	0	0	177
2	27	6	8	1	29	1	0	0	72
3	3	0	0	0	0	0	0	0	3
4	0	0	0	0	0	0	1	0	1
5	1	0	0	0	0	0	0	0	1
Total	1319	2304	344	70	46	2	3	0	4088

Results

A total of 331 patients had completed the trial up to 31 December 2002, of whom 253 had more than one follow-up assessment. Therefore, there were 331 patients available with a first assessment, 253 with a last assessment and seven sites for each of these patients at both time-points, a total of 4088 observations. However, data for either or both of the nurses' assessments at one or more of the sites were missing for 1482 observations (36%). There were 234 instances where WNs gave partially missing data (i.e. not missing for all sites) (55) or completely missing data (179); for CRNs there were 189 such cases (173 with partially missing data and 16 with data missing for all sites).

Pressure ulcer diagnosis: all sites

There was 98.9% agreement between the CRNs and WNs in the diagnosis of a pressure ulcer (*Table 69*).

Both CRNs and WNs agreed on grading 2548 observations as 'no pressure ulcer' and 31 observations of 'pressure ulcer'. However, the high prevalence of 'no pressure ulcer' masks the poor agreement between CRNs and WNs in the diagnosis of a pressure ulcer. The CRNs recorded 15 pressure ulcers when the WN did not; conversely, the WN recorded 12 pressure ulcers when the CRN did not.

Skin classification

Agreements between the CRNs and WNs for the 4088 observations for all grades are pooled overall (all sites) in *Table 70*. Data for either or both of the nurses' assessments at one or more of the sites are missing for 1482 observations. Of the remaining 2606 assessments there was a total of 590 (23.0%) disagreements between the CRNs and WNs. Of the disagreements, 514 were one grade different (0 and 1a, 1a and 1b, etc.), 70 were two grades different, including 0 and 1b (55) and 1a and 2 (15), and six were more than two grades different, including 0 and 2 (6).

Levels of agreement were similar for each skin site and also for the first and last CRN assessment dates.

Summary and discussion: CRN and WN agreement

Overall percentage agreement and kappa statistics indicate 'good' agreement between the CRNs and WNs, but important disagreements in both the diagnosis of pressure ulcers and skin classification for all grades are concealed by the high

prevalence of normal skin with no skin changes. The results of the two studies comparing CRN and WN skin assessments raise important issues in relation to the limitations of summary measures for inter-rater agreement, problems associated with the diagnosis of early pressure ulcers which impact upon the derivation of the primary end-point and concerns regarding the levels of missing WN follow-up data.

As a test statistic, kappa can verify that agreement exceeds chance levels; however, there has been controversy over its use to quantify the level of agreement among two or more raters.[88–91] One of the difficulties is that kappa can be affected in complex ways by the presence of bias between raters. In this study, however, there is approximate symmetry between the two discordant proportions (*Table 68*); hence, there appears to be no systematic difference in the way in which the nurses use the skin classification scale. That is, WNs did not appear to underestimate or overestimate any more than the CRNs, and there is no obvious bias.

Another difficulty associated with the use and interpretation of kappa is that its value depends on the proportion of subjects (prevalence) in each category.[87] This is clearly a limitation in this study, where the majority of skin sites had no pressure ulcer identified by either the CRN or WN (*Table 67*). This dependency of the kappa statistic is particularly illustrated in the kappa calculated for the skin site right hip (*Table 66*). Only one disagreement was observed (percentage agreement 99.7%), yet the 95% confidence interval of the kappa statistic indicates that the true value of kappa lies between 'poor' and 'very good' agreement.

Translated overall, the kappa statistic for CRN and WN agreement in the pretrial substudy, for all skin sites pooled together, is 'good' (*Table 66*). If the CRNs are taken as the gold standard, the proportion of pressure ulcers correctly identified by the WNs is 144 out of 186 (77.4%) (*Table 67*). Alternatively, the proportion of no pressure ulcers correctly identified by the WNs is 2175 out of 2210 (98.4%). However, these percentages are influenced by the high prevalence of 'no pressure ulcer'.

Indeed, the high prevalence of skin areas assessed as having no pressure ulcer conceals the level of disagreement between CRNs and WNs in identifying pressure ulcers. In the pretrial substudy, of the 186 pressure ulcers reported by the CRNs, 42 (22.6%) were not identified by the WNs (under-reporting) (*Table 67*). Despite this relatively poor agreement of pressure ulcer diagnosis, the kappa statistic and its 95% confidence interval for all skin sites suggest 'good' agreement between raters. These proportions, however, assume that the CRN assessments are always 'correct' and that within- and between-CRN variability does not exist. Clearly, this cannot be assumed, so these results should not be over-interpreted.

Overall, both studies suggest that, even when a pressure ulcer is defined as a grade 2 skin lesion, there are important differences in the reporting of ulcers by qualified ward-based nursing staff and expert nurses. While some of the disagreements are simply the result of site confusion (e.g. between left and right skin sites), in relation to trial design the lack of reliability in grade allocation by body site has consequences in the derivation of the end-point. In addition, both studies identified a small but important number of skin areas that were more than two grades different. There was also an important number of patients where the CRN recorded a grade 2 or above pressure ulcer when the WN did not and the WN recorded a pressure ulcer when the CRN did not.

Finally, the trial data inter-rater reliability assessment identified a large amount of missing data; almost 40% of the data were missing on the dates of the CRN assessments; that is, even on the days when ward staff were reminded or prompted by the CRN to complete the case report form there were large amounts of missing data.

Implications for statistical analysis

In the PRESSURE Trial daily skin assessments were proposed for two main reasons: accurate recording of all pressure ulcers for the derivation of the primary end-point (previous research using daily skin assessments revealed that some pressure ulcers resolve within periods as short as 24 hours[35,36]) and accurate recording for the derivation of secondary end-points, including time to pressure ulcer development and time to healing. Previous experience had suggested that in a trial situation designated qualified ward nursing staff skin assessment records were reliable, but the number of wards involved was smaller and the follow-up period of short duration (1 day postoperatively), so the associated workload was minimal.[35]

However, the important issues raised by the pretrial inter-rater reliability substudy and

assessment of trial data were discussed by the TSC and TMG on 24 April 2002.

The TSC and TMG were reassured that the CRNs working across different hospital sites were able to assess and record skin observations in a consistent and reliable way. However, there was concern about the level of disagreement between the CRNs and WNs in the classification of skin assessments.

In light of the concerns raised about the quality of WN data it was recommended by the TSC that the CRN data should be used for the main trial analysis. The advantage of using CRN data was that the data are reliable. The disadvantage was that pressure ulcers of short duration would not be recorded and the secondary end-points of time to development and time to healing would be on a ± 4 days basis. It was felt that, in relation to the former, if the pressure ulcers are of such short duration they are not clinically important and, in relation to the latter, this would apply to patients in both groups.

It was agreed also that the WN data should continue to be obtained for the purposes of verification, since skin assessment data were not systematically and routinely recorded in many of the participating clinical areas, and source data verification was not feasible. It was also recommended that the change to the statistical analysis plan should remain confidential to the TSC and TMG and not be relayed to the CRN team leader or CRNs. There was a concern that the CRNs should not know that their data would have primacy, in order to avoid their changing their behaviour in relation to their assessment and recording of skin observations, and to maintain their motivation to prompt WNs in recording the trial data. The latter would be used to verify CRN data (when manually checking forms) and log the day of any mattress changes. It would also be used in a sensitivity analysis, to test the robustness of the results given by CRN data.

Appendix 13

Classification of Skin Assessment Comments

Skin comments at baseline (F2) and eligibility (E1) to identify the variables 'skin alteration/trauma' and 'wound' for the adjusted analysis

Five categories have been determined as follows:

1 = Skin trauma at baseline
All skin sites will be included in the primary analysis; 'skin trauma' will be included as a risk variable for adjusted analysis.

2 = Wound at baseline
Skin sites will be excluded from primary analysis; 'wound' will be included as a risk variable for adjusted analysis.

3 = Pressure ulcer at baseline
The comment is irrelevant as a grade ≥ 2 has been identified at baseline. It is coded so that we can pull this out later to look at diagnostic uncertainty.

4 = Dressing at baseline
Skin sites will be excluded from primary analysis; this category will be included in 'wound' as a risk variable for adjusted analysis.

5 = Irrelevant comment

Detail categorisation

1 = Skin trauma/skin alteration

Grade 0–1b or missing plus descriptors

Skin trauma descriptors include:
- Blisters
- Breaks
- Bruising
- Calcaneum ischaemic
- Cellulitis
- Cracks
- Discoloration
- Dry
- Eczema
- Excoriated
- Flaky
- 'Fragile' skin
- Graze
- Hard/calloused
- Inflamed
- Ischaemic
- Itchy
- Lesion
- Soft
- Sore
- Spongy
- Lipodermatosclerosis
- Lymphodema – exudating
- Macerated
- Painful varicose veins
- 'Papery thin' skin
- Peripheral cyanosis
- Poor circulation
- Previously healed pressure ulcer
- Psoriasis
- Rash
- Reaction to brace
- Refill sluggish
- Scab
- Scar
- Scaly
- Scratches
- Scuffs
- 'Skin condition'
- Spots
- Tender
- Warty lesion

Skin trauma descriptors excluded and coded 5 (see below):
- Red
- Pink
- Not broken
- Area *x* cm by *x* cm

2 = Wound
(a) Grade 0–1b or missing plus description including:
- Surgical wound
- Leg ulcer
- Diabetic ulcer
- Ischaemic ulcer
- Vascular ulcer

(c) Grade ≥ 2 BUT pressure ulcer at randomisation = no

(d) For 'skin comments – other sites' if assessment = missing then wound includes descriptors:
- Laceration
- With steristrips
- Skin tear
- Necrotic

3 = Pressure ulcer plus comment
Grade ≥ 2 AND pressure ulcer at randomisation = yes

4 = Dressing
Skin site excluded from primary analysis

Descriptors include:
- Dressing
- Bandage
- Four-layer bandage
- Area covered

5 = Irrelevant comment

Appendix 14

Mattress Model Categories

Category type	Model
Trial overlay	Debut (mattress overlay) Alpha Xcell Not specified[a]
Trial replacement	Debut (mattress replacement) Nimbus 2 Nimbus 3 Nimbus (not specified)[a] Not specified[a]
Equivalent overlay	Alto
Equivalent replacement	Nimbus 1 Cavalier Duo
Foam	High density Templur Med Link Nurse Transfoam Prima foam Permaflex foam Vapalux foam Key2care Disc Prima Premier Slumberland Pink Pentaflex Body foam Soft Form Vaperm Pegasus Foam Permalux Harvest Healthcare Pink Mattress Harvest MSS
Foam equivalent	Spenco Spenco + Prima foam Repose
Other non-trial	Auto Xcell Pegasus Primo Huntleigh Breeze Hill Rom Evolution Clinirest Pegasus Key 2 Care Pegasus Airwave Huntleigh Oasis Air Fluidised Bed Clinirest Alpha Care Plus Profiling Bed Air Mattress Airflow Flex replacement Regular mattress

[a] 'Not specified' = Correct mattress type from correct manufacturer for that centre, but no details of model given on the case report form.

Appendix 15

Mattress Acceptability Coding Schema for Patient Comments

Temperature = 1
- 1.1 = Hot/too warm
- 1.2 = Sweaty/sticky
- 1.3 = Cold/cool
- 1.4 = Other: Environmental or other reasons for temperature perception
  - Itchy
  - Damp
  - Warmer (not necessarily a bad thing)

Motion of mattress = 2
- 2.1 = Negative
- 2.2 = Positive (e.g. comfortable)
- 2.3 = Equivocal
- 2.4 = Unknown

Subcategories for 2.1, 2.2 and 2.3
- 1 = Sleep
- 2 = Nausea
- 3 = Lumpy/ridges/hard/uncomfortable/feels like a hole in bed
- 4 = Cycle/vibrating/tipping sensation/ strange
- 5 = Painful/affects or uncomfortable on back/felt lump on back
- 6 = Felt might fall/did fall
- 7 = Noise/hisses when moves
- 8 = Other: couldn't settle/made want to micturate/feeling dizzy

For example, 2.17 = disliked noise of bed; 2.24 = found bed's motion comforting.

Movement of person = 3
- 3.1 = Getting into and out of bed
- 3.2 = In bed
- 3.3 = Positive (e.g. able to use ridges to push self up)
- 3.4 = Equivocal

Subcategories for 3.1, 3.2 and 3.4
- 1 = Height
- 2 = Insecure/safety worry/slide sideways/feels surface uneven
- 3 = Soft edges/too soft/lack of support/hands sink in/difficult to grip
- 4 = Ridges/mattress shape/hollows in mattress
- 5 = Other: other reasons for problems/difficult to use bedpan/not got out of bed yet

For example, 3.24 = problem moving in bed because of ridges.

General mattress characteristics = 4
- 4.1 = Mattress not working/not working properly/did not sleep on mattress
- 4.2 = Hard to tuck sheet under/sheets come off or gather/mattress cover slips
- 4.3 = Mattress/bed too high
- 4.4 = Mattress slippy/slipped
- 4.5 = Mattress too soft/edges soft or slope
- 4.6 = Not able to use backrest
- 4.7 = Other: mattress smells/dye comes out of mattress

Appendix 16

Quality of Life Substudy: Patient Information Sheet

Living with a pressure sore – the patient's perspective

You are being invited to take part in a research study. Before you decide it is important for you to understand why this research is being done and what it will involve.

Please take time to read the following information carefully and discuss it with your relatives and ward nurse if you wish. Ask if there is anything that is not clear or if you would like more information.

Take time to decide whether or not you wish to take part. Your involvement is entirely voluntary. If you do decide to take part you will be asked to sign a consent form. You will be able to leave the study at any time, without giving a reason. This will not affect any aspect of your care.

If you decide not to take part this will not affect any aspect of your care.

Background to the study

Pressure sores, also called bedsores, develop in a small number of people admitted to hospital. They have many causes and we are studying the best beds and mattresses for preventing them. As part of this study of beds and mattresses we would like to find out what difference having a pressure sore makes to patients.

What would the study involve?

We are asking patients with pressure sores to agree to be interviewed on two separate occasions, approximately 2 months apart, by a research nurse. These interviews would be tape-recorded and then typed out in full. The information will be used to assess the benefit to patients of preventing a sore.

You will be asked about your general health, how you felt about having a sore, whether it is painful, and how you find having dressings replaced. We would like to interview you now and when your pressure sore has healed.

All information that is collected about you during the course of this study will be strictly confidential. Your name and personal details will be removed so that you cannot be recognised.

What will happen to the results of this study?

This study will lead to a better understanding of how pressure sores affect people's lives. This information will be used in a large study of beds and mattresses to help us assess which system should be used in the NHS.

Administrative information

This study has been commissioned by the National Health Service Research and Development Programme – *Health Technology Assessment*.
The funding has enabled us to employ a research nurse to interview patients. She is not involved in your care in any way and is not employed by the hospital or community.

The multi-centre research ethics committee and the local research ethics committee have approved this research.

Thank you for considering this study. If you have any questions about the study at any time, please contact:

Andrea Nelson
Department of Health Studies
University of York, YO10 5DD
Tel: 01904 434110

[NB. The Department of Health Sciences was formerly known as the Department of Health Studies, therefore both names appear.]

Appendix 17

Quality of Life Substudy: Interview Schedule

Introduction to the PRESSURE study

The PRESSURE Trial has been commissioned by the NHS to find out whether alternating pressure mattress replacements are any better at preventing and healing pressure ulcers than alternating pressure overlays. Approximately 2000 people from seven hospitals around the UK are being recruited into a study to help us answer this question.

Introduction to the research

As part of the study we are looking at the cost of pressure ulcers. We are looking at the cost to the NHS of treating pressure sores AND the cost to patients of having a sore. To find out what impact a pressure sore has on quality of life, I am interviewing around 20 people with pressure ulcers. The objective is to find out more about the experience of having a pressure ulcer and how it affects their overall health.

I would like to interview you again in between 8 and 12 weeks. This will help us find out whether any changes in your pressure sore, such as it getting smaller, make a difference to the effect it has on your quality of life.

Tape-recording and anonymity

Spoken by researcher – "I would like to make a tape-recording of this interview as that will help make sure I catch everything you say. We think it is better than my taking notes. Before we start, can I just confirm that you are happy with that? Now what will happen to this tape is that I will take it back and our conversation will be typed out in full. When we do that we make sure that there is nothing in the document that could identify you – so for example the name of the hospital, or ward would be blanked out. Similarly names of any people you mention will be blanked out or changed so that you can remain anonymous."

Interview schedule

1. Background
   a. Household composition
   b. Employment activity

2. General health
   a. How would you describe your general health?
   b. What do you know about pressure sores/ulcers/bedsores?

3. This illness episode
   a. When were they first taken ill?
   b. Hospital admission
   c. When did they notice problems with skin?

4. Their pressure ulcer
   a. When did it start?
   b. What did they think about it?
   c. What treatments were used?
   d. What were you told about the pressure ulcer?
   e. When did you see it?
   f. How did you feel about the ulcer?
   g. Is the ulcer painful at all?

5. What impact has the sore had on you?

6. Treatments
   a. What treatments have you had on your pressure ulcer?
   b. How often is the sore treated?
   c. What is the treatment like?

Is there anything you'd like to tell me about the sore and its treatment?

Reiterate about anonymity

Thank you

Appendix 18

Quality of Life Substudy: Letter to Arrange Second Interview

THE UNIVERSITY of York

DEPARTMENT OF HEALTH SCIENCES

Seebohm Rowntree Building (Area 4)
Alcuin College
Heslington
York YO10 5DD

Telephone 01904 321349
Fax 01904 321739
Email ean2@york.ac.uk

www.york.ac.uk/healthsciences

«Date»

Dear

RE: A study of pressure ulcers – their impact on people's life

I saw you in hospital on the «Date_seen_» this year and talked to you about having a pressure ulcer (also known as a pressure sore). At that time I mentioned that I would like to follow you up after discharge from hospital, and I am writing to ask if it would be possible for me to visit you at home on «Date_of_app», in the morning, say «Time_of_app»? The purpose of my visit would be to ask you some questions about your health in general, and in particular about the pressure sore you have had.

I would be grateful if you would let me know whether this time or date is convenient. You can do this:
By telephoning me on 01904 321349 OR
By completing the attached page and sending it to me in the stamped addressed envelope enclosed.

Please do not hesitate to contact me should you require any further information.
Kind regards

E Andrea Nelson PhD RN
Senior Research Fellow

REPLY LETTER

THE UNIVERSITY of York

DEPARTMENT OF HEALTH SCIENCES

Seebohm Rowntree Building (Area 4)
Alcuin College
Heslington
York YO10 5DD

Telephone 01904 321349
Fax 01904 321739
Email ean2@york.ac.uk

www.york.ac.uk/healthsciences

«Date»

Dr Andrea Nelson
Dept Health Sciences
Seebohm Rowntree Building (area 4)
University of York
York YO10 5DD

RE: A study of pressure ulcers – their impact on people's life (REF «Ref»)

Please let me know whether it is convenient for me to visit you at home on «Date_of_app» at «Time_of_app»

You can do this by:

Telephoning 01904 321349 and speaking to Andrea Nelson (or leaving a message if outside office hours).

Complete and return this page in the stamped addressed envelope.
Please tick a box indicating whether it is convenient to visit you at home.

It is convenient for me to be visited by Andrea Nelson on «Date_of_app» at «Time_of_app» ☐

2. It is not convenient for me to be visited by Andrea Nelson on «Date_of_app» at «Time_of_app» and I would like to suggest another date (write one in below): ☐

3. It is not convenient for me to be visited by Andrea Nelson on «Date_of_app» at «Time_of_app» and I would prefer not to arrange another date. ☐

SIGNED _____ («forename» «surname»)

Appendix 19

Letter Inviting CRNs to Participate in Focus Group

THE UNIVERSITY of York

DEPARTMENT OF HEALTH SCIENCES

Area 2 (1st Floor)
Seebohm Rowntree Building
Heslington
York YO10 5DD

Direct Line (01904) 321331
Fax (01904) 321383
Email ks25@york.ac.uk

«Date»

Dear [insert name],

PRESSURE Trial: Focus group with Clinical Research Nurses

We would like to invite you to participate in a focus group for Clinical Research Nurses (CRN) on the PRESSURE Trial. As a current (or past) CRN, you have valuable experiences and observations related to this project. We would like to use the focus group as an opportunity to explore these views and gain further understanding of the contexts in which the study took place. In particular, we would like to explore with you:

1. Your general experiences of being a CRN for the PRESSURE Trial.
2. Your observations of pressure area care practices specifically related to the trial.
3. Your general observations of pressure area care practices in the clinical settings.

Your experiences and observations are very important because you are able to provide contextual details that are of direct relevance to the reporting of the PRESSURE Trial.

What would be involved?
We would like to invite you to participate in this focus group on Tuesday 9 March 2004 at 11.00am. For your convenience, the group has been scheduled to coincide with your next CRN meeting at the Clinical Trials Research Unit (Leeds University). The focus group provides an opportunity for you to share and discuss your views with other CRNs on the three areas outlined above. The focus group will last no more than $1\frac{1}{2}$ hours and will be facilitated by myself (Karen Spilsbury) and Emily Petherick. We are both Research Fellows, working with Professor Nicky Cullum and Dr Andrea Nelson, in the Department of Health Sciences (University of York).

With your permission, the focus group will be audiotaped to enable an accurate record of the group discussions to be captured and Emily will also record fieldnotes. The tape will then be transcribed to facilitate analysis. The tapes will only be listened to by the research team and will not be used for any other purpose than the research. The tape and fieldnotes will be kept in a locked filing cabinet until completion of the study and the transcript will be anonymised. Whilst quotes generated from the focus group will be used in reports and publications, it will not be possible to identify individual participants (or Trusts) in any of these research outputs. You are assured of anonymity and confidentiality.

Thank you for taking the time to read this information. We hope that you are able to participate in the focus group because it is an important part of the PRESSURE Trial study. Please do not hesitate to contact me if you have any questions or concerns about the focus group.

At the focus group I will reinforce this information, outline how the focus group will be conducted and offer an opportunity for you to ask questions or raise any concerns. If you are satisfied with the information provided and happy to participate in the focus group you will be asked to sign a consent form (copy included) to comply with the requirements of research governance.

We look forward to meeting you in March.

Yours sincerely,

Dr Karen Spilsbury (Research Fellow)

cc. Emily Petherick (Research Fellow)
cc. PRESSURE Trial Management Committee

Appendix 20

Invitation Letter for Telephone Interviews with CRNs from Centres not Represented at the Focus Group

THE UNIVERSITY of York

DEPARTMENT OF HEALTH SCIENCES

Area 2 (1st Floor)
Seebohm Rowntree Building
Heslington
York
YO10 5DD

Direct Line (01904) 321331
Fax (01904) 321383
Email ks25@york.ac.uk

«Date»

Dear [insert name],

PRESSURE Trial: Telephone interview with Clinical Research Nurses unable to participate in March focus group

You may remember that I contacted you earlier this year, asking if you would participate in a focus group (9 March, 2004) for Clinical Research Nurses (CRN) on the PRESSURE Trial. I understand that at the time you were unable to attend the focus group. Thank you for giving this matter your consideration.

Nine of your colleagues, from five of the participating centres in the PRESSURE Trial, were able to take part. The focus group generated a lively discussion and highlighted the valuable experiences and observations of CRNs related to the project. However, a couple of centres were not represented at the focus group. This includes your centre, [insert name of centre]. I am keen to explore with you whether issues raised in the focus group are also applicable to your centre. I would therefore like to offer you the opportunity of participating in a telephone interview to explore:

1. Your general experiences of being a CRN for the PRESSURE Trial
2. Your observations of pressure area care practices specifically related to the trial
3. Your general observations of pressure area care practices in the clinical settings

Your experiences and observations are very important because you are able to provide contextual details that are of direct relevance to the reporting of the PRESSURE Trial.

If you are willing to participate, I will arrange an interview with you. My background is general nursing and I have eight years' research experience. I am currently a Research Fellow, working part-time with Professor Nicky Cullum and Dr Andrea Nelson, in the Department of Health Sciences (University of York).

The interview will last approximately 30 minutes and I will ask some general questions about your experiences and observations and some more specific questions based on issues raised by the focus group. With your permission, the interview will be tape-recorded and data will be used to supplement the focus group analysis and inform the final report of the PRESSURE Trial. I will be the only person to listen to the tape and it will not be used for any other purpose than the research. The tape will be kept in a locked filing cabinet and any notes made from the interview will be anonymised. Whilst quotes generated from both the interviews and focus group are being used in reports and publications, it will not be possible to

identify individual participants (or trusts) in any of these research outputs. You are assured of anonymity and confidentiality.

Thank you for taking the time to read this information. I hope that you are able to participate in an interview because it is an important part of the PRESSURE Trial study. If you are happy for me to interview you please could you contact me directly so that you can have an opportunity to ask any questions or raise any concerns. If you are then satisfied with my responses and happy for the interview to go ahead I will ask you to return the consent form (included) to comply with the requirements of research governance. We can then arrange a suitable time for the telephone interview to take place.

I look forward to hearing from you.

Yours sincerely,

Dr Karen Spilsbury (Research Fellow)
Department of Health Sciences
University of York

01904 321331
07980 420707
ks25@york.ac.uk

The PRESSURE Trial – HTA Ref 97/ 06 14; *NRR ID N0484070431*

Consent Form for Interviews with Clinical Research Nurses

Please read this form carefully and ask if there is anything that you do not understand.

Name …… Job Title: Clinical Research Nurse

Organisation ……

Please tick box if you agree with the statement

I have received and read an information sheet and understand what the telephone interview aims to do ☐

I have had an opportunity to ask questions and clarify anything that I do not understand ☐

I understand that a researcher from the University of York will carry out the telephone interview ☐

I understand that all information collected from me for the study will be kept confidential and that the only people who see this information are researchers at the University of York ☐

I understand that the information gathered will be used to write research articles and reports, but will not identify me by name, nor will it identify the Trust concerned by name unless the Trial Management Committee feel that patient safety is compromised by not so doing, in which case I will not be identified but relevant information will be conveyed to the Chief Nurse ☐

I have not been placed under any pressure to participate ☐

I have considered all the information provided and I am happy to take part in this study ☐

I freely give my consent to take part in a telephone interview

Signature …… Date ……

I have given written information and a verbal explanation to the above named person who has given their consent to participate in the focus group

Investigator's Signature …… Date ……

Appendix 21

Consent Form for CRN Focus Group

The PRESSURE Trial – HTA Ref 97/ 06 14; *NRR ID N048407043 1*

Please read this form carefully and ask if there is anything that you do not understand.

Name …… Job Title: Clinical Research Nurse

Organisation ……

Please tick box if you agree with the statement

I have received and read an information sheet and understand what this focus group aims to do ☐

I have had an opportunity to ask questions and clarify anything that I do not understand ☐

I understand that researchers from the University of York will facilitate the focus group interview ☐

I understand that all information collected from me for the study will be kept confidential and that the only people who see this information are researchers at the University of York ☐

I understand that the information gathered will be used to write research articles and reports, but will not identify me by name, nor will it identify the Trust concerned by name unless the Trial Management Committee feel that patient safety is compromised by not so doing, in which case I will not be identified but relevant information will be conveyed to the Chief Nurse. ☐

I have not been placed under any pressure to participate ☐

I have considered all the information provided and I am happy to take part in this study ☐

I freely give my consent to take part in this focus group

Signature …… Date 09-03-04

I have given written information and a verbal explanation to the above named person who has given their consent to participate in the focus group

Investigator's Signature …… Date 09-03-04

Appendix 22

Structure for CRN Focus Group

This is only an overview of the focus group. The structure is flexible so that the discussion is guided by the Clinical Research Nurses (CRNs).

Prompts will be used, such as:

- **Would you explain that further?**
- **Can you give me an example?**

(1) Group introductions (5 minutes)
- Karen Spilsbury – Research Fellow: facilitate group discussion
- Emily Petherick – Research Fellow: co-facilitate group discussion, responsible for recording equipment and taking notes
- Participants – name, location, length of time as CRN, previous roles/background (brief) – equipped with skills for role as CRN

(2) Overview of focus group and opportunity for questions (10 minutes)
- Use handout as guide
- Gain consent
- ***Start tape recording***

General questions outlined below but aim is to get CRNs to expand and identify important factors:

(3) Focus 1 – Experience as CRN (30 minutes)

What have been your experiences of being a CRN? (Good/bad)
- Response of staff – randomisation/engagement with study
- Support from Trust
- Motivation during the trial (isolation/working in different way/how keep motivated)
- Staff preconceived ideas about pressure care/mattresses

(4) Focus 2 – Observations of pressure care (specific to trial and generally in clinical settings) (30 minutes)
The aim is to get CRNs to discuss *good* and *bad* practices:

(a) **What have been your observations of pressure care specific to the trial?**
- Documentation – quality, accuracy, presence/absence, errors
- What was your experience of getting the right mattress to patients in the trial? Was this influenced by hospital/ward ownership or use of supplier?
- Did ward staff have preconceived ideas about – which mattress might be better? The effects of different mattresses? What have nurses said in relation to different mattresses?
- The ward staff were not blind to the intervention – did this have any effect on the trial?
- When were mattresses changed? Why were they changed? Did this fit with the protocol? To what extent were CRNs involved in decisions to upgrade a mattress?

(b) **What have been your general observations of pressure care in the clinical settings?**
- Treatment – how staff respond when a patient has a pressure sore – turning/beds
- Prevention – skin inspection, regular risk assessment, repositioning, use of nutritional supplements, etc.
- What was the ward culture like – is pressure care high on the nursing agenda?

(5) Ending (5 minutes)

- Have your observations of pressure care (as part of your role as CRN) been generally positive or negative?

(6) Summary (2 minutes)

- Key elements of discussion

(7) Final opportunity for comments (8 minutes)

The aim of today's discussion was to explore your experience of being a CRN and to gather your observations of pressure care specific to the trial and general observations in clinical settings. You have provided valuable feedback. However, is there anything else we have missed or should have talked about that you would like to raise before the group finishes?

- *Thank participants.*
- *Remind them that PRESSURE Trial report will be using data generated during discussion to provide contextual detail.*
- *Reiterate confidentiality and anonymity.*
- ***Turn off tape recorder.***

Appendix 23

Letter Inviting CRNs to Participate in a Follow-up Telephone Interview (Post-focus Group)

THE UNIVERSITY of York

DEPARTMENT OF HEALTH SCIENCES

Area 2 (1st Floor)
Seebohm Rowntree Building
Heslington
York
YO10 5DD

Direct Line (01904) 321331
Fax (01904) 321383
Email ks25@york.ac.uk

«Date»

Dear [insert name],

PRESSURE Trial: Follow-up telephone interviews with Clinical Research Nurses

Thank you for participating in the Clinical Research Nurse (CRN) focus group earlier this year. Your contribution to the group was much appreciated and the group discussion generated valuable data for the PRESSURE Trial report.

The focus group was transcribed and I have subsequently been analysing the content and processes of the group discussion. The findings have been drafted for the PRESSURE Trial report but I am keen to carry out follow-up interviews to clarify some issues in each of the represented centres. As a CRN representing [insert name of centre], I wonder if you would be happy to take part? If you are willing to participate, I will arrange a telephone interview with you at a time most convenient for yourself because I understand that you have since moved on from your CRN role into a new position.

The interview will last approximately 30 minutes. The purpose of this follow-up interview is:

1. To provide an opportunity for you to comment on the focus group experience;
2. To ensure you felt you had the opportunity to share your experiences and observations;
3. To allow you an opportunity to make further contributions if you feel there were experiences and observations that you did not have the chance to share during the focus group;
4. To provide an opportunity for me to ask you some specific questions arising from the analysis and to check out some of the emerging findings;
5. To provide an opportunity for me to ask you about the *treatment* of pressure sores because the focus group did not fully address this.

With your permission, the interview will be tape-recorded and data will be used to supplement the focus group analysis and inform the final report of the PRESSURE Trial. I will be the only person to listen to the tape and it will not be used for any other purpose than the research. The tape will be kept in a locked filing cabinet and any notes made from the interview will be anonymised. Whilst quotes generated from both the interviews and focus group are being used in reports and publications, it will not be possible to identify individual participants (or Trusts) in any of these research outputs. You are assured of anonymity and confidentiality.

Thank you for taking the time to read this information. I hope you might be able to participate in this follow-up interview? If you are happy for me to interview you please could you contact me directly so that you can have an opportunity to ask any questions or raise any concerns. If you are then satisfied with my responses, and happy for the interview to go ahead, I will ask you to return the consent form (included) to comply with the requirements of research governance. We can then arrange a suitable time for the telephone interview to take place.

I hope your new job is going well. Thank you again for the time you have given to this project. I look forward to hearing from you.

Yours sincerely,

Dr Karen Spilsbury (Research Fellow)
Department of Health Sciences
University of York

01904 321331
07980 420707
ks25@york.ac.uk

The PRESSURE Trial - HTA Ref 97/ 06 14; *NRR ID N0484070431*

THE UNIVERSITY of York

Consent Form for Follow-up Interviews with Clinical Research Nurses

Please read this form carefully and ask if there is anything that you do not understand.

Name …… Job Title: Clinical Research Nurse

Organisation ……

Please tick box if you agree with the statement

I have received and read an information sheet and understand what the telephone interview aims to do ☐

I have had an opportunity to ask questions and clarify anything that I do not understand ☐

I understand that a researcher from the University of York will carry out the telephone interview ☐

I understand that all information collected from me for the study will be kept confidential and that the only people who see this information are researchers at the University of York ☐

I understand that the information gathered will be used to write research articles and reports, but will not identify me by name, nor will it identify the Trust concerned by name unless the Trial Management Committee feel that patient safety is compromised by not so doing, in which case I will not be identified but relevant information will be conveyed to the Chief Nurse ☐

I have not been placed under any pressure to participate ☐

I have considered all the information provided and I am happy to take part in this study ☐

I freely give my consent to take part in a telephone interview

Signature …… Date ……

I have given written information and a verbal explanation to the above named person who has given their consent to participate in the focus group

Investigator's Signature …… Date ……

Health Technology Assessment Programme

Prioritisation Strategy Group

Members

HTA Commissioning Board

Members

Current and past membership details of all HTA 'committees' are available from the HTA website (www.hta.ac.uk)

Diagnostic Technologies & Screening Panel

Members

Chair,
Dr Ron Zimmern, Director of the Public Health Genetics Unit, Strangeways Research Laboratories, Cambridge

Ms Norma Armston, Lay Member, Bolton

Professor Max Bachmann Professor of Health Care Interfaces, Department of Health Policy and Practice, University of East Anglia

Professor Rudy Bilous Professor of Clinical Medicine & Consultant Physician, The Academic Centre, South Tees Hospitals NHS Trust

Dr Paul Cockcroft, Consultant Medical Microbiologist and Clinical Director of Pathology, Department of Clinical Microbiology, St Mary's Hospital, Portsmouth

Professor Adrian K Dixon, Professor of Radiology, University Department of Radiology, University of Cambridge Clinical School

Dr David Elliman, Consultant Paediatrician/ Hon. Senior Lecturer, Population Health Unit, Great Ormond St. Hospital, London

Professor Glyn Elwyn, Primary Medical Care Research Group, Swansea Clinical School, University of Wales Swansea

Mr Tam Fry, Honorary Chairman, Child Growth Foundation, London

Dr Jennifer J Kurinczuk, Consultant Clinical Epidemiologist, National Perinatal Epidemiology Unit, Oxford

Dr Susanne M Ludgate, Medical Director, Medicines & Healthcare Products Regulatory Agency, London

Professor William Rosenberg, Professor of Hepatology, Liver Research Group, University of Southampton

Dr Susan Schonfield, Consultant in Public Health, Specialised Services Commissioning North West London, Hillingdon Primary Care Trust

Dr Phil Shackley, Senior Lecturer in Health Economics, School of Population and Health Sciences, University of Newcastle upon Tyne

Dr Margaret Somerville, PMS Public Health Lead, Peninsula Medical School, University of Plymouth

Dr Graham Taylor, Scientific Director & Senior Lecturer, Regional DNA Laboratory, The Leeds Teaching Hospitals

Professor Lindsay Wilson Turnbull, Scientific Director, Centre for MR Investigations & YCR Professor of Radiology, University of Hull

Professor Martin J Whittle, Associate Dean for Education, Head of Department of Obstetrics and Gynaecology, University of Birmingham

Dr Dennis Wright, Consultant Biochemist & Clinical Director, Pathology & The Kennedy Galton Centre, Northwick Park & St Mark's Hospitals, Harrow

Pharmaceuticals Panel

Members

Chair,
Dr John Reynolds, Chair Division A, The John Radcliffe Hospital, Oxford Radcliffe Hospitals NHS Trust

Professor Tony Avery, Head of Division of Primary Care, School of Community Health Services, Division of General Practice, University of Nottingham

Ms Anne Baileff, Consultant Nurse in First Contact Care, Southampton City Primary Care Trust, University of Southampton

Professor Stirling Bryan, Professor of Health Economics, Health Services Management Centre, University of Birmingham

Mr Peter Cardy, Chief Executive, Macmillan Cancer Relief, London

Professor Imti Choonara, Professor in Child Health, Academic Division of Child Health, University of Nottingham

Dr Robin Ferner, Consultant Physician and Director, West Midlands Centre for Adverse Drug Reactions, City Hospital NHS Trust, Birmingham

Dr Karen A Fitzgerald, Consultant in Pharmaceutical Public Health, National Public Health Service for Wales, Cardiff

Mrs Sharon Hart, Head of DTB Publications, *Drug & Therapeutics Bulletin*, London

Dr Christine Hine, Consultant in Public Health Medicine, South Gloucestershire Primary Care Trust

Professor Stan Kaye, Cancer Research UK Professor of Medical Oncology, Section of Medicine, The Royal Marsden Hospital, Sutton

Ms Barbara Meredith, Lay Member, Epsom

Dr Andrew Prentice, Senior Lecturer and Consultant Obstetrician & Gynaecologist, Department of Obstetrics & Gynaecology, University of Cambridge

Dr Frances Rotblat, CPMP Delegate, Medicines & Healthcare Products Regulatory Agency, London

Professor Jan Scott, Professor of Psychological Treatments, Institute of Psychiatry, University of London

Mrs Katrina Simister, Assistant Director New Medicines, National Prescribing Centre, Liverpool

Dr Richard Tiner, Medical Director, Medical Department, Association of the British Pharmaceutical Industry, London

Dr Helen Williams, Consultant Microbiologist, Norfolk & Norwich University Hospital NHS Trust

Therapeutic Procedures Panel

Members

Chair,
Professor Bruce Campbell,
Consultant Vascular and General Surgeon, Department of Surgery, Royal Devon & Exeter Hospital

Dr Aileen Clarke,
Reader in Health Services Research, Public Health & Policy Research Unit, Barts & the London School of Medicine & Dentistry, London

Dr Matthew Cooke, Reader in A&E/Department of Health Advisor in A&E, Warwick Emergency Care and Rehabilitation, University of Warwick

Dr Carl E Counsell, Clinical Senior Lecturer in Neurology, Department of Medicine and Therapeutics, University of Aberdeen

Ms Amelia Curwen, Executive Director of Policy, Services and Research, Asthma UK, London

Professor Gene Feder, Professor of Primary Care R&D, Department of General Practice and Primary Care, Barts & the London, Queen Mary's School of Medicine and Dentistry, London

Professor Paul Gregg, Professor of Orthopaedic Surgical Science, Department of General Practice and Primary Care, South Tees Hospital NHS Trust, Middlesbrough

Ms Bec Hanley, Co-Director, TwoCan Associates, Hurstpierpoint

Ms Maryann L Hardy, Lecturer, Division of Radiography, University of Bradford

Professor Alan Horwich, Director of Clinical R&D, Academic Department of Radiology, The Institute of Cancer Research, London

Dr Simon de Lusignan, Senior Lecturer, Primary Care Informatics, Department of Community Health Sciences, St George's Hospital Medical School, London

Professor Neil McIntosh, Edward Clark Professor of Child Life & Health, Department of Child Life & Health, University of Edinburgh

Professor James Neilson, Professor of Obstetrics and Gynaecology, Department of Obstetrics and Gynaecology, University of Liverpool

Dr John C Pounsford, Consultant Physician, Directorate of Medical Services, North Bristol NHS Trust

Karen Roberts, Nurse Consultant, Queen Elizabeth Hospital, Gateshead

Dr Vimal Sharma, Consultant Psychiatrist/Hon. Senior Lecturer, Mental Health Resource Centre, Cheshire and Wirral Partnership NHS Trust, Wallasey

Dr L David Smith, Consultant Cardiologist, Royal Devon & Exeter Hospital

Professor Norman Waugh, Professor of Public Health, Department of Public Health, University of Aberdeen

Expert Advisory Network

Members

Professor Douglas Altman, Director of CSM & Cancer Research UK Med Stat Gp, Centre for Statistics in Medicine, University of Oxford, Institute of Health Sciences, Headington, Oxford

Professor John Bond, Director, Centre for Health Services Research, University of Newcastle upon Tyne, School of Population & Health Sciences, Newcastle upon Tyne

Mr Shaun Brogan, Chief Executive, Ridgeway Primary Care Group, Aylesbury

Mrs Stella Burnside OBE, Chief Executive, Office of the Chief Executive. Trust Headquarters, Altnagelvin Hospitals Health & Social Services Trust, Altnagelvin Area Hospital, Londonderry

Ms Tracy Bury, Project Manager, World Confederation for Physical Therapy, London

Professor Iain T Cameron, Professor of Obstetrics and Gynaecology and Head of the School of Medicine, University of Southampton

Dr Christine Clark, Medical Writer & Consultant Pharmacist, Rossendale

Professor Collette Clifford, Professor of Nursing & Head of Research, School of Health Sciences, University of Birmingham, Edgbaston, Birmingham

Professor Barry Cookson, Director, Laboratory of Healthcare Associated Infection, Health Protection Agency, London

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Feedback

The HTA Programme and the authors would like to know your views about this report.

The Correspondence Page on the HTA website (http://www.hta.ac.uk) is a convenient way to publish your comments. If you prefer, you can send your comments to the address below, telling us whether you would like us to transfer them to the website.

We look forward to hearing from you.

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